

Class 1 Devices

Case Studies in Medical Devices Design

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DEDICATION

This book is dedicated to anyone who has never
had a book dedicated to them before.
(If you are reading this, does this mean you?)

ACKNOWLEDGEMENTS

I would like to acknowledge the contributions of the FDA, the MHRA, and the EU to this text. In addition, I would like to thank those who agreed to contribute to the case studies, in particular, Intelligent Orthopaedics Ltd and Onbone Oy. Of course, I am grateful to my editor, Fiona, at Elsevier who kept me on track. Lastly, but not least, I also thank my family for keeping me on track.

Introduction

This book complements the original text in *Medical Devices Design: Innovation from Concept to Market*¹ (from now on I am going to call this the *reference text*). The intention of this book, and its sister books in the series, is to support the concepts presented in the reference text through case studies. In the context of this book, the case studies consider Class I (EU) and 510(k) exempt (FDA).²

1.1 REMINDER CONCERNING CLASSIFICATION

Before we go any further with our discussions, we should remind ourselves about classification systems. In the European Union, there are four levels of classification, classes I, IIa, IIb and III. We are only considering those in Class I.³ In the USA, the FDA system is different but similar; the classification we are considering is 510(k) exempt. We will be examining the classification of a device within one of the case studies in this text. We will be looking at making a classification in the next chapter.

What does a Class I or 510(k) exempt classification mean for a medical devices company? It *does not mean* that the design rigour is any less; it simply means the application process for clearance to market in the EU or in the USA is easier than for the others.

Note: This textbook, nor any textbook, is a classification bible. One should *always* refer to the current information to perform classification

¹You should have a copy of this text, a copy of the Medical Devices Directive, and a copy of CFR 21 with you at all times – the last two being mandatory. A copy of ISO 14971 is also mandatory and ISO 13487 would be of great benefit.

²**Note:** The USA have class I 510(k) exempt AND class II 510(k) exempt. In the EU, the equivalent is Class I only.

³**Note:** Class I Sterile packed and Class I with Measuring Function *do not* fall into this category.

of a medical device. The only sources one should ever use are the EU and FDA website. Never use an out-of-date guideline, book or pamphlet; that way, madness lies!

1.2 A REMINDER CONCERNING THE IMPORTANCE OF DESIGN RIGOUR (OR DESIGN CONTROL)

Quite often, I have to talk to students concerning design rigour and the question comes back – why? It is very simple. One day, and I hope never, you may be in a criminal court because your device has hurt someone, potentially seriously. If you have not followed a rigorous design process, you should be prepared for a long holiday in a not-so-nice government funded resort. If you want to avoid a stay in prison, then why not simply do things properly from the start? As we say in England, this is a no brainer!

This text represents neither design theory nor design analysis. This subject matter is covered in the main text that this book refers to (the reference text). You should read the main book before attempting to go any further. Do not rely on this text alone.

1.3 A REMINDER CONCERNING UNDERSTANDING THE PROBLEM

One of the biggest frustrations I have when talking to some ‘medical devices designers’ is their lack of any clinical experience. Indeed, I have heard it said that they do not want to understand clinical practice as it ‘limits their ability to design’. That is complete and utter rubbish. To design anything, one must understand, fully, the issues: the environment, the political, the social and the economic. If you do not appreciate what the problem is, and where the boundaries are, then you cannot design a commercially viable device. You may well have a device, but it will not be one you can ever be proud of; it will become a millstone around your neck⁴ and you *will* live to regret it.

⁴An old saying that comes from the Bible, Luke 17:2, ‘It were better for him that a millstone were hanged about his neck, and he cast into the sea, than that he should offend one of these little ones’. It now means a burden one has to bear, forever.

1.4 A REMINDER CONCERNING A TEAM/HOLISTIC APPROACH

When you start your design process, you have to define the *design* team. As stated in the reference text, include as many of your subcontractors as possible, at the earliest stage possible. This includes manufacturers, packaging suppliers and shippers. Include end users and their support staff. Get as much input into your designs as possible, as soon as possible. Do not sit yourself in an ivory tower pretending to be the ‘design guru’ that all bow down to. No man is an island, no matter what Simon and Garfunkel say.⁵

Teamwork is an essential part of design. A good designer needs to be able to bounce ideas off others and accept their critical feedback when it is given. No one is the sole expert on anything: opinions differ, attitudes differ and skills differ. You need to be able to *Design for All*, and not just design for one. You will only succeed in achieving this outcome if you operate with a team philosophy.

Remember to look at your project with a ‘wide-angled lens’. Focusing on minutiae will not help you in the end. Be holistic in your approach; adopting a team philosophy is a start. However, you need to consider the project as a whole. If you do not, something will come back and ‘bite you’ at the very end, and design changes late in a project drive up costs astronomically.

1.5 A REMINDER CONCERNING COSTS

Research and development can be a very expensive business. Not only can you be stripped of cash by overuse of consultants but also the very cost of essentials can be daunting. Prototypes can be very costly, simply because they are prototypes. You will, undoubtedly, underestimate the time you will spend on the project, but you must try to avoid to. Design projects can get a life of their own and can act as a cash ‘*black hole*’, sucking in funds for little or no return. Work out a project budget and stick to it: do not be tempted to say to yourself ‘only need to spend a little more’; ‘just a little further’; ‘not quite right yet...a little more’.

⁵‘I am a rock, I am an island’ lyrics from a Simon and Garfunkel song.

One of the biggest issues is to know when to stop. Design teams can go on *ad infinitum* making ever more small changes, but only for changes sake. Determine the value of design modifications before going ahead. If a small change increases the value by 100%, so be it. But, if the change costs more than the potential benefit, why do it? Be strict with yourself, and that is one of the hardest things to do.

1.6 INTRODUCTION TO THE CASE STUDIES

As described previously, a number of case studies are to be used to provide the backbone of worked examples to enhance the content of the reference text. The bases of the case studies for this book are those considered to be either Class I (EU) or 510(k) exempt (FDA).

The case studies are drawn from a variety of disciplines. However, one should not assume that because a pertinent discipline to one's own area is missing that the content is, somehow, of no interest. The case studies are there as vehicles for application only. One can apply the principles to any discipline. Therefore, it is important that you look at each case study as a whole and do not skip examples because they are not in your discipline. If you do this, you may miss an important point that could be applicable across the board. Equally, skipping concepts that appear to be of no interest is not a good design practice. A good designer looks across disciplines with a 'designer's eye': in this way, the designer's skills can only be enhanced; in this way, the designer can pick up examples of good practice; and, finally, in this way, their own products may just become that little bit better.

Case Study: The OTC Joint Support

If you have ever sprained a wrist, twisted your knee or strained the ligaments of your ankle, you will be well aware of the over-the-counter (OTC) elasticated support. In the past, these were simple elasticated hose; however, nowadays, there are a plethora of items from simple elasticated hose through to velcro-attached mechanical structures. However, they all have one thing in common; in the EU, they are Class I devices, and in the USA, they are, generally, Class I/510(k) exempt.⁶

⁶An addendum to this are those supplied in a sterile condition that are not in this category.

This case study brings the concept of OTC products to medical devices. I am amazed how many times I have heard the comment ‘oh it’s not a medical device as it is only for sale to the general public and not to a hospital’ – wrong! Any simple analysis of the medical devices regulations, across the World, shows the most Hogarthian⁷ of designers that they are indeed *medical devices* designers.

Figures 1.1–1.3 illustrate the range of devices that fall into this category. All three figures are, effectively, for the same thing. They all



Fig. 1.1. Simple elasticated support.

⁷Hogarth was an artist of the early eighteenth century (1697–1764). He was particularly famous, amongst other things, for cartoon characters known as Hogarthian Grotesques whose visualisations hyper-extended their personal traits.



Fig. 1.2. Neoprene knee support using 'hook and loop tape' strapping.

provide some form of support for areas about the knee. However, their complexity increases from [Figures 1.1–1.3](#).

[Figure 1.1](#) illustrates a simple elasticated bandage. This is normally in some form of tubular fashion and is a mix of textiles and elastic material. The object of the hose is to provide compression, and it is an elasticated textile; this is all it can provide. It has no structural stability and can provide no axial or bending support at all.

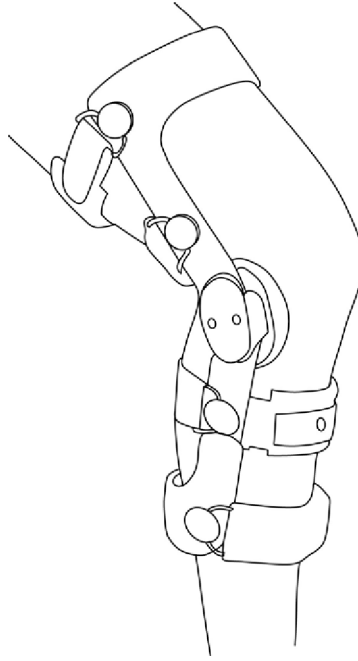


Fig. 1.3. Knee brace using frameworks and hook and loop strapping.

Figure 1.2 gives an example of the influx of new materials to this discipline. Neoprene has been incorporated to not only give the elasticated nature of the support, but also adds other beneficial properties. The addition of a Velcro® (or hook and loop) strap allows the end user to create mechanical compression in addition to any elastic compression; it also adds enhanced location.

Figure 1.3 illustrates a functional knee brace. In these types of devices, the compression provided by the straps is for location only; it is the ‘mechanical scaffolding’ that provides axial, torsional and bending support. Normally, there is little compression.

Case Study: Surgical Wire Cutters

This case study gives an example of a reusable surgical device. These types of devices are commonplace in every hospital, and the example could, just as easily, have been a pair of forceps, or a trocar. The important concept in this case study is that it has to be used over and over again, and therefore has to be cleaned and resterilised over and over again. This puts its own tensions into the design process and its own stresses on the device itself. Again, the later chapters put this into context.

Figures 1.4–1.7 illustrate four forms of wire cutter in common use in the operating room.

Figure 1.4 illustrates the type of cutter that one would find in any operating room; they are also very similar to the type of cutters one would purchase for clipping one's toe nails or for cutting electrical wires. Therefore, these are simple evolutions from cutters used in other disciplines.

Figure 1.5 is an evolutionary step from the cutter illustrated in Figure 1.4. It incorporates mechanical advantage by using the mechanism

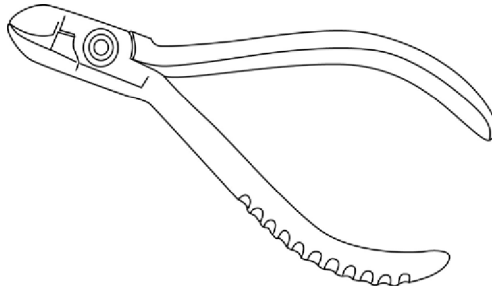


Fig. 1.4. Surgical wire cutters with no mechanical advantage.

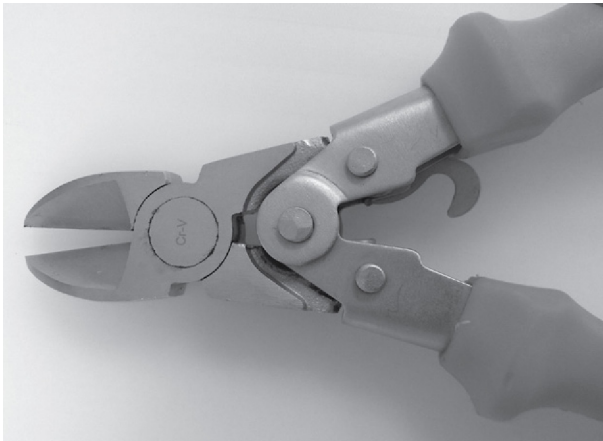


Fig. 1.5. Standard cutters with mechanical advantage.



Fig. 1.6. Parallel cutters with high mechanical advantage.



Fig. 1.7. Specialist large diameter wire cutters using shearing rather than a cutting action.

highlighted in the figure. This is a linkage system that amplifies the force created by the grip of the hand (which will be examined in more detail later).

Figure 1.6 is another evolution of that illustrated in Figures 1.4 and 1.5. In this situation, the cutters act, almost, parallel to one another. This minimises the tendency for the wire to be forced out of the cutter. Furthermore, this type of cutter has replaceable cutting blades – a major advantage over the previous two examples.

Figure 1.7 is a complete deviation from the previous examples of cutters. The previous cutters work on the basis of having a sharp edge being forced into a wire and eventually breaking through (see Figure 1.8a). This cutting action can leave a sharp edge on the cut surface. This example actually puts the rods into shear (Figure 1.8b). This is a completely different process and relies on the rod failing in ‘shear’. The advantage here is that the process can result in no sharp edges.

Case Study: Orthopaedic Cast

Once again, this is a simple device that has been in use, probably, since the first broken leg or arm was treated. Once again, there are a number of forms. The first is a simple splint; the second is an inflatable splint; the third is the standard plaster-of-Paris cast; and its evolution into the fourth that is a cast using more modern materials. This case study enables the discussion to examine the level of how temporary a device is; it also looks at reuse of a device that may not be sterilised using autoclave, ethylene oxide or irradiation.

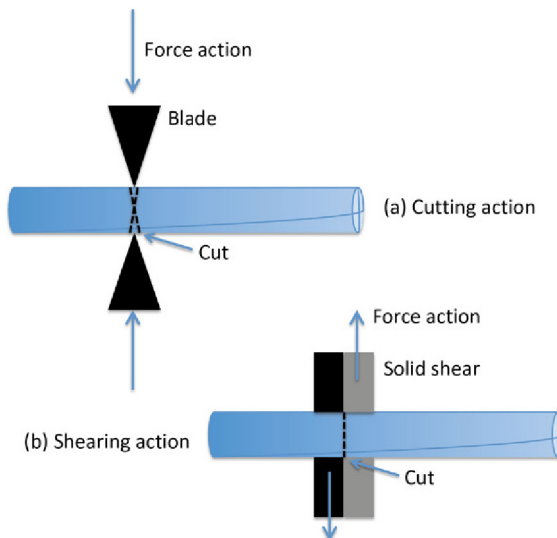


Fig. 1.8. Illustration of the differences between the cutting actions.

Figures 1.9 and 1.10 illustrate simple splints. They come in a variety of forms, all for slightly different purposes. However, they all have one single purpose that is common: they provide immediate, but temporary, support for an injured limb, joint or bone. In some cases, they are disposable after use, but in other cases, they can be reused. Probably, the

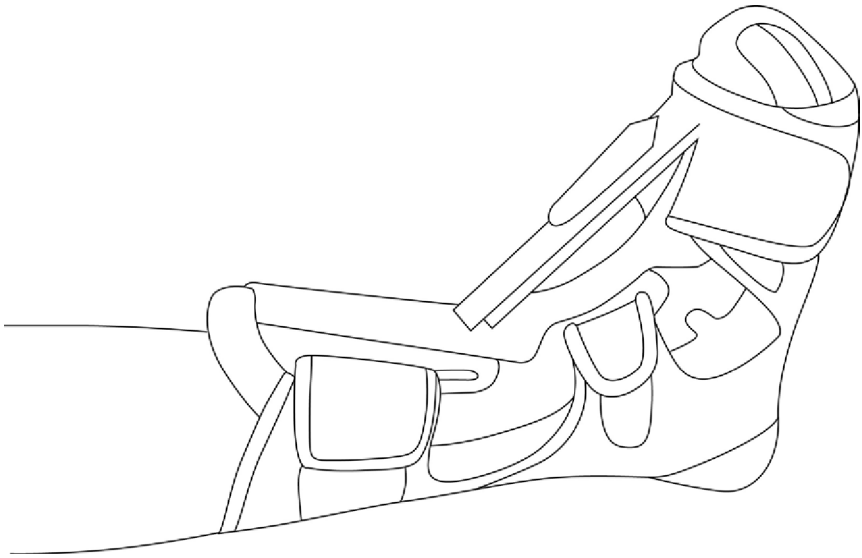


Fig. 1.9. Splint for the support of the ankle.

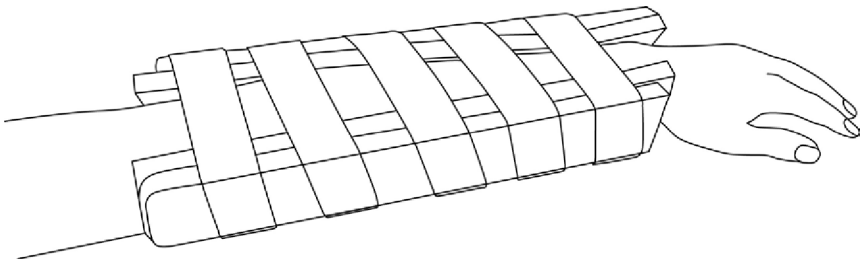


Fig. 1.10. A temporary forearm splint.

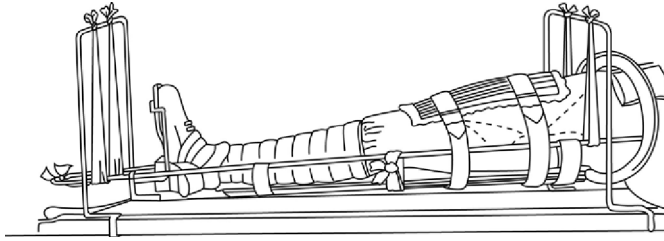


Fig. 1.11. An early reproduction of a Thomas splint.

most famous medical splint is the Thomas splint (Figure 1.11). This was invented by Hugh Owen Thomas⁸ in 1875 and has changed little since. However, this type of Traction Splint is *not* temporary but can be used for some time.

Figure 1.12 illustrates a variation on a theme, the inflatable splint. In this situation, the limb is surrounded by a plastic bag that is inflated. The static pressure within the bag not only compresses the tissues but also gives rigidity to the structure, forming a temporary cast. These are now commonplace in emergency vehicles.

Figures 1.13 and 1.14 illustrate typical orthopaedic casts for the support of damaged limbs. Figure 1.13a is the classic plaster-of-Paris cast as most people over the age of 40 will remember. Those attending emergency departments for fractures nowadays will be able to pick colours opposed to the traditional white; this is due to the use of modern materials to act as the support (Figure 1.13b). However, an even more novel approach is illustrated in Figure 1.14; this is a wood-based casting material and is, therefore, arguably the most environmentally friendly of the whole.

⁸To orthopaedic surgeons, Thomas is a legend. His early works and devices are still on display at the British Orthopaedic Association HQ in London. He is to orthopaedics what WG Grace is to cricket. His father was a 'bone setter' orthopaedic surgeons did not exist, but his son is renowned for starting the discipline and is known as their collective 'father'.



Fig. 1.12. An inflatable cast.

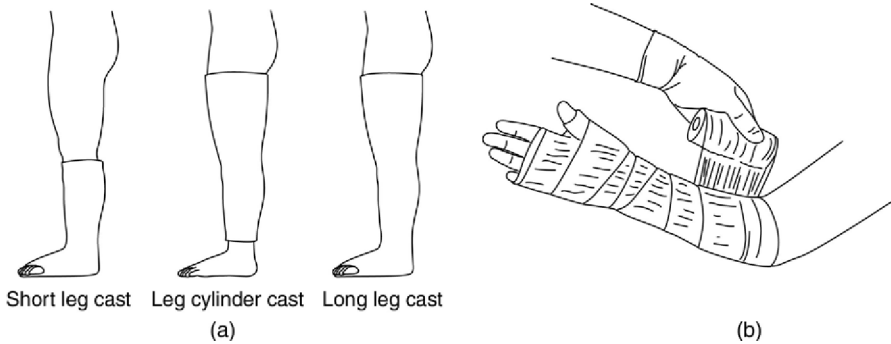


Fig. 1.13. Orthopaedic cast.

The reader may be asking why the author has grouped all of these disparate devices into one group. The reason is that they all perform, roughly, the same function – to provide non-invasive mechanical support over a period of time.



Fig. 1.14. Renewable material cast (courtesy Onbone Oy).

1.6.1 Comments Concerning the Case Studies

The case studies described in the previous sections are the basis for the exemplification of the material presented in the original textbook; the essence of all future discussions will be around these. I will try to cover all aspects of concern for Class I/510(k) exempt devices; as a consequence, some further examples will be drawn for comparison, but these will be explained as we meet them.

I am hoping that the case studies I have drawn are widely known, and therefore, will make sense to any reader. I could have selected highly technical, research-led examples, but I suspect these will have left confusion where understanding is required. Therefore, if I seem to be going over simple concepts, please remember that other readers will find these concepts challenging and bear with me; I have to cater for all audiences.

1.7 HINTS TO ENABLE YOU TO UNDERSTAND THE TEXT

Throughout the book, I will be referring to both EU and FDA regulations; therefore, it is a good idea to have access to both close-by. I promise you, they are not something to try and memorise! Also, you would be advised to have a copy of ISO 13485 and ISO 14971 too.

For those of you who have read the preceding text,⁹ please go back and look at this chapter again. For those of you who have not, go and get it and read the chapter!

⁹Ogrodnik, P. (2012) *Medical Devices Design*. Academic Press, Oxford.

Oh, this is supposed to be a case study book. This means *I do not* do all of the work, you have to do some too. Therefore, I will not address each of the case studies in every chapter, some of them will be the basis of case studies for *you* to complete using the MDD, the FDA, and *the* text book as your references; you will also need to talk to people, use a library and read some research papers! At the end of the day, that is the idea of this text to prepare you to classify, document and successfully file your own device, so why not practice on someone else's first!

CHAPTER 2

Classification

2.1 INTRODUCTION

In this chapter, we will be using the case studies to examine how a classification is discerned. In *all* of these cases, there is a precedent on which to make a judgement. This text is *not* considering those devices for which there has never been anything like it before (consider the first ever X-ray machine). In nearly every medical device case study I have been involved with, there has been a precedent on which to base a judgement. That does not mean that I have been lucky, or have not been involved in anything new – it simply means I have looked hard and done my research to ensure that I have not missed something obvious that will make my life easy. It is much easier for someone else to say ‘Oh that’s new it will need a real detailed examination’, their job is done and yours has started. For you, it is much easier to say, ‘this is very similar to.... And hence it is ...’ and then let them do the work!

2.1.1 Timing

Unfortunately, most designers leave this part of the medical devices design process to the last. People tend to worry about the route to CE mark of FDA clearance to market at the end.

My response to this predicament is: NO!

You should be looking at the potential classification at the start of the process. Then, as the design progresses, you can keep checking that a design change or a nuance has not altered the classification to a higher level; because if it does, then the rigour you need to apply also increases.

Therefore, my suggestion to all budding, and established, medical device designers is to do a preliminary classification first, check your classification as you go along and finalise the classification at the end (refer to Case Study ‘Surgical Wire Cutters’ Chapter 1).

2.2 FDA CLASSIFICATION

Unlike the MDD, the FDA classifies each device and stores this in a very large database. Therefore, all one needs to do is to trawl the classification index using a search engine. As most of you know, search engines are great if you know the keyword, terrible if you do not! Therefore, the very start of the process is to list as many keywords that describe your device as you can. Do not forget spelling, and do not forget terminology – this is the USA; therefore, those designers from the EU must get used to using words spelled in US English and use the terminology of the USA. I assure you they are not the same!

2.2.1 Keywords

Let us examine the device and suggest some keywords.

Obviously, wire cutters spring to mind as does the single use of the term cutter. But, what other words could we use?

A handy hint here is to have a couple copies of a thesaurus handy: one would be an English version and the other a copy of a Webster's Thesaurus for the US terminology. In addition, do not forget that there are people who are 'in the know'; these are your end users. Do not be afraid to ask them for help on keywords! And, one last bit of advice, even though I hate it, is good old Google and Wikipedia; one may question the content one finds, but one thing they have in common that is invaluable is 'keywords'. Therefore, with a bit of spadework, one can generate a list of keywords to use in the FDA search engine:

- from *cutter*, we get snips, scissors and clippers.
- from *wire*, we get surgical wire, Kirschner, k-wire and cable.

As you can see, it does not take long to get the list, but *one does need to use one's imagination*.

All one needs to do now is to enter the FDA website, go to medical devices, and then use the Product Classification¹ search engine. Using the search *wire cutter* ends with a result like this.

¹At the time of press, this was <http://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cf-PCD/PCDSimpleSearch.cfm>

But, do keep an eye on this as websites do have a habit of moving around!



Fig. 2.1. Result from FDA search using the keyword ‘wire cutter’ (courtesy FDA).

to 10 of 31 Results for wire

1234>

Results per page10

New Search

Export To ExcelHelp

Product Code	Device Name	Regulation Number	Device Class	
NJA	Accessory, System, External Fixator, Containing An	Smooth Or Threaded Metallic Bone Fixatio...	888.3040	2
OWI	Bone Fixation Cerclage, Sublaminar	Bone Fixation Cerclage	888.3010	2
NJM	Bracket, Ceramic, Orthodontic	Orthodontic Plastic Bracket	872.5470	2
OFB	Catheter Guide Wire Kit	Catheter Guide Wire	870.1330	2
ECN	Clamp, Wire, Orthodontic	Orthodontic Appliance And Accessories	872.5410	1
EJW	Clasp, Wire	Preformed Clasp	872.3285	1
NNN	Crimper, Wire, Ent, Non-Sterile	Prosthesis Modification Instrument For O...	874.3540	1
JXT	Crimper, Wire, Ent, Sterile	Prosthesis Modification Instrument For O...	874.3540	1
HXZ	Cutter, Wire	Orthopedic Manual Surgical Instrument	888.4540	1
NNP	Die, Wire Bending, Ent, Non-Sterile	Prosthesis Modification Instrument For O...	874.3540	1

Fig. 2.2. Result of FDA classification search using the keyword ‘wire’ (courtesy FDA).

Figure 2.1 has been taken straight from the search engine. Oh dear! First thought is that we have a new device that will need to go through a lengthy process. But, we now use the term *wire* on its own. Why? I hear you ask. Because, I answer, if the device is a wire cutter, then it is likely to have *wire* in the title, as it is likely to have something like *Cutter* (Figure 2.2). However, they may not be in the order you think they are. Here is the result.

Look at the second from bottom result ‘Cutter, Wire’. Is this not our answer? And, it is! Straightaway, we can see that our product code is HXZ, and using regulation 888.4540, our device is Class I. Delving deeper, by clicking on the device name, gives a full description (Figure 2.3). Not only is the device Class I, it is 510(k) exempt: parties and cream buns all round!

2.3 EU MDD CLASSIFICATION

Using the Medical Devices Directive rule system, we work through each rule from Rule 1, until we come to an obvious stop. However, it is a good practice to go through all of them just to make sure we do not miss

FDA Home Medical Devices Databases

New Search		Back To Search Results
Device	Cutter, Wire	
Regulation Description	Orthopedic manual surgical instrument.	
Regulation Medical Specialty	Orthopedic	
Review Panel	Orthopedic	
Product Code	HXZ	
Premarket Review	Office of Device Evaluation (ODE) Division of Orthopedic Devices (DOD) Joint and Fixation Devices Branch Two & Hips/Wrists/Fingers (JFDB2)	
Submission Type	510(K) Exempt	
Regulation Number	888.4540	
Device Class	1	
Total Product Life Cycle (TPLC)	TPLC Product Code Report	
GMP Exempt?	No	
Note: FDA has exempted almost all class I devices (with the exception of reserved devices) from the premarket notification requirement, including those devices that were exempted by final regulation published in the <i>Federal Registers</i> of December 7, 1994, and January 16, 1996. It is important to confirm the exempt status and any limitations that apply with 21 CFR Parts 862-892. Limitations of device exemptions are covered under 21 CFR XXX.9, where XXX refers to Parts 862-892. If a manufacturer's device falls into a generic category of exempted class I devices as defined in 21 CFR Parts 862-892, a premarket notification application and fda clearance is not required before marketing the device in the U.S. however, these manufacturers are required to register their establishment. Please see the Device Registration and Listing website for additional information.		
Recognized Consensus Standards		
● ASTM F665-04 (Reapproved 2013) Standard Practice for Care and Handling of Orthopedic Implants and Instruments ● ASTM F1089-10 Standard Test Method for Corrosion of Surgical Instruments ● ISO 13402 First edition 1995-08-01 Surgical and dental hand instruments – Determination of resistance against autoclaving, corrosion and thermal exposure ● ISO 7153-1 Second edition 1991-04-01 Surgical instruments – Metallic materials – Part 1: Stainless steel (including: Amendment 1 (1999))		
Third Party Review	Not Third Party Eligible	

Fig. 2.3. Regulation in detail (courtesy FDA).

something that has changed or altered or has some nuance that makes our device a higher classification.

Unfortunately, it is not as quick a process as the FDA; unless you happen to be Rule 1! Before we start though, we need to look at the terminology used in Annexure IX and apply this to our device: this will help us in our deliberations.

- Duration of use:
Transient: Normally intended for continuous use for less than 60 minutes.
Short term: Normally intended for continuous use for not more than 30 days.
Long term: Normally intended for continuous use for more than 30 days.

(EU, 1993)

I cannot see wire cutters being used for 60 minutes! Definitely transient.

- Invasive devices:
Definitely non-invasive, using any of the definitions.

- Reusable surgical instrument:

Instrument intended for surgical use by cutting, drilling, sawing, scratching, scraping, clamping, retracting, clipping or similar procedures, without connection to any active medical device and which can be reused after appropriate procedures have been carried out.

(EU,1993)

Definite yes!

- Active Medical Device:

No

- Active Therapeutic Device:

No

- Active Device for Diagnosis:

No

Therefore, let us start with Rule 1...

Rule 1

All non-invasive devices are in Class I, unless one of the rules set out hereinafter applies.

(EU, 1993)

Well, that looks pretty conclusive to me! But, before we get too excited, we must read the end of the sentence: ‘unless one of the rules set out hereinafter applies’. A pretty obvious hint to keep on looking; careful consideration shows that there are no further rules that apply. Therefore, the statement for this device would be:

According to Annex IX, Rule 1 this device is Class I.

This means that the device is CE marked in the EU by simple self-certification with the host country’s notified body.²

2.4 YOUR TURN

As stated earlier, it is not my intention to work through every case study. The only way for you to learn to do things for yourself is to do some controlled case studies by yourself. In the case of this text, all the devices are either EU Class I and/or USA 510(k) exempt.

²The notified body, if you recall, is the main point of contact for the Medical Devices Directive in a single country (in the United Kingdom, the MHRA). One only needs to register in one EU state and that covers registration in all states.

Homework

You should prove that all the devices are classified as such using the procedure highlighted previously.

Starter for Ten³

Just to get you going, here are the answers for the Thomas splint:

FDA:

Product Code HSP

Regulation: 888.5890

Class: Class I 510(k) exempt

EU:

According to Annexure IX Rule 1, this device is Class I.

You should check whether the above are correct statements and then repeat the process for all examples as given in Chapter 1.

³A 'starter for ten' comes from the UK quiz show University Challenge, where a batch of subsequent questions were given to the team who correctly answered a first question, which was their 'starter for ten'. It is also the title of a comic romance novel and film.

CHAPTER 3

Taking the Design from Idea to PDS

3.1 INTRODUCTION

In this chapter, we will be concentrating on the implementation of the design process and further assuming that our goal is to achieve a fully functioning device. It will demonstrate that the ‘Specification’ stage is critical to this process.

In this chapter, we will use the case studies to examine various aspects of the process leading to the generation of a product design specification (PDS). As with the previous chapter, it will be left to you to complete the task for the other case studies.

3.2 DEVELOPING THE SPECIFICATION

If ever there was one issue in design, which is both the most critical and the most neglected, it is the specification phase. As stated in the reference text, it is this phase that not only demonstrates that you understand what is required of the device but also demonstrates ‘design input’. The influence of end users, patients, and so forth, on the design of your device has to be demonstrable, and it is the specification that enables you to do this clearly and coherently. A further point to consider is that if the specification is written well, then virtually all of the hard work has been done; all we need to do now is be innovative in selecting a solution.

3.2.1 The Need

We have seen the final outcomes of knee supports in Chapter 1. But, in this case study, we are going to turn this on its head and try and start from scratch. What if we were given the task to develop a new knee support – how would we go about starting off the design process?

The first part is to establish the need. Have we been asked to do a me-too (i.e., copy something); are we evolving from an established design; or are we starting from scratch with a new concept. It is the need that gives us this information. Here are three scenarios:

1. *Marketing have just come back from an exhibition in Fort-Worth. They saw a new elasticated tube bandage for knee support that had different colours, depending on the size of the tube. This replaced boxes of small, medium, and large, and changed the sizes in terms of diameter. They saw that the stand was very successful and thought this a good idea; could we do the same?*
2. *Marketing have just come back from an exhibition in Fort-Worth. They saw a range of elasticated tube bandage suppliers for knee support and noticed that everyone still had the bandages supplied as small, medium, and large. Could we develop a range that was based on leg diameter, as this could be a market differentiator?*
3. *Marketing have just come back from an exhibition in Fort-Worth. They saw a range of elasticated tube bandage suppliers for knee support. They stated that this market was saturated with the same old thing. Is there any new technology that could give us a market edge over the traditional suppliers?*

Which of the above statements relates to me-too, evolutionary, and customer led? Not too hard really: 1 = me-too (scavenging need); 2 = evolutionary need; 3 = immediate need.

Of course, there is one more, which is where technology drives the need (such as the Sony Walkman). One could say that Sony created the need, but you can bet your last dollar that the Sony board had identified that the customer would want this before they ploughed millions of Japanese Yen into its development.

How would statements 1, 2 and 3 affect the way we wrote the need for the design process that is to follow? The biggest difference would be how we would define market size. In the case of statements 1 and 2, we would be looking to poach a small amount of market share from our competitors. In the case of statement 1, the best we could hope is to cut the price to achieve market gain. In statement 2, we are using design to achieve market gain and may be able to command the same price but

with a better margin. In statement 3, it is unlikely we could persuade buyers to move from existing suppliers without either a reduction in price (or similar price) or by providing some form of cost-of-procedure reduction or major clinical benefit by use of a slightly more expensive item.

You can see how defining the need begins to focus the mind. After all, a ‘me-too’ is not much of a design challenge; it is copying plain and simple. The need in this type of design scenario is all around IP busting; can we get around the patent? Does a patent exist or has it lapsed? Does the patent cover a state we are already in and could exploit, if not? Do not be fooled; this goes on all of the time. In some cases, it is upfront and legal, but hidden behind is a world of copyright theft where products are being illegally counterfeited and sold on as the ‘real thing’; we are not talking about that here. In this case, it is a legitimate business question (just think about the rise of the touch screen telephone!).

The big question in all of these is to determine market size. The board, your bank, or your spouse is going to have to agree with the finances for the design; therefore, you need to make a case before you go ahead. How would we find this out? Unfortunately, there is an expensive way and a moderately expensive way. The expensive way is to buy a business report.¹ Here, you would be paying for someone else’s legwork. The moderately expensive way is to do the legwork, yourself. There are a range of databases and statistic sites to choose from. One of the most useful is the episode statistics of the NHS in the United Kingdom; using this is a source that enables you to calculate, quickly, the number of episodes per 1 million head and therefore have a guide for other countries. The next thing to do is to find a friendly purchasing officer in a local hospital/clinic and ask them – you can only get a refusal and they do not hurt, honestly! In addition, this device is an OTC product, who sells it? Probably, a pharmacy, another source of information!

¹Business reports by, say, Frost & Sullivan are freely available at a cost, often \$1000.

Why am I stressing so much on this aspect? Simply put, you need to be able to make money from your design; therefore, the potential investment has to be paid back – in spades! If not, why bother?

Case Study: OTC Knee Support

A quick search of news items found a Forbes press release stating that the number of US citizens having knee problems will be 70 million in 2020. We can be very superficial and suggest we will attack 5% of this market – 3.5 million people. Which is equivalent to 14,000 per million head of population. 100% is 280,000 per million head of population. I do not know about you, but if I saw a target market of 3.5 million units per annum, I would start to find real estate agents to look for a bigger house. All I have done is scraped the surface – there is even more data to be found.

What is the average price we are looking at? A quick trip to a pharmacy shows us that the OTC price ranges from £2 to £20 (\$3 to \$30) for a simple elasticated knee bandage. This suggests a market of between £7–£70 million (\$12–\$120 million). Once again, I am beginning to smile.

Assuming we are working with scenario 2, the example of statement of need would be as given in Figure 3.1. Now the wording given in [the figure](#) may well be rough and ready, but it is a start. It is likely that there will be further discussion required, but the point of the matter is that if it does go forward, your mind is focused on the task ahead. You have identified the ‘one thing’ and, even better, the target sales price!

Description of Need

Marketing have identified that changing the sizing of an elasticated knee bandage from being in small, medium and large to being defined by leg diameter will provide a significant market differentiator.

Initial market research suggests that a 5% market share would be circa 14,000 units per million head of population; this in turn leads to a sales value of between \$7 and 70 million depending on the sales price we would command. The point of sales price ranges from \$3.5 to 35.

When matured the US market could support sales of 3.5 million units per annum.

An initial classification suggests it is class I 510(k) exempt in the USA and Class I in the EU.

Fig. 3.1. Example statement of need.

Homework

Your task: yep you should have been expecting this! Now that you have seen what is required for this case study, try to replicate the statement of need for all of the other case studies in turn. The important thing here is that you already know the outcome; therefore, you are imagining what drove the people to produce the solution... the answer to WHY? (and do not say 'why not?').

3.2.2 The PDS

This section is the most problematic for people not used to writing specifications. For some strange reason, everyone assumes the PDS, or Technical Specification is the final outcome: a little handbook that goes in the packaging with the product: a little handbook that says what batteries to use, what size it is, what weight it is, and so forth. *It is not!* The PDS is the starting point. It is the document that demonstrates that you fully understand what is required from a functional, end user, environmental, and so forth, perspective. It is the one document that shows you have asked for 'design input'. That is why, I labour the point *so much!* Get the PDS right and all else falls into place. Before we go any further, you *must* read the relevant chapter in the reference text; I will not be saying this again as I am, now, going to assume that you have done so.

Once the need has been established (as illustrated in [Figure 3.1](#)), we need to add 'flesh to the bones'. Nobody could take that as a simple statement of need and come up with a coherent solution; they may come up with 'A' solution, but it will not be coherent, optimal, or meet the actual need. Therefore, the object of the PDS is to start asking relevant questions. This is the point at which you start to call meetings and focus groups. This is the point where you get the potential end users together and start to ask them the awkward questions that need answering. This is the point where you get every book on the clinical procedure in question and find out everything you need to know about how it is going to be used and why/what for. End user input is extremely important for two reasons: a) it helps with your sales strategy and b) it is a fundamental requirement for both FDA and Medical Devices Directive (MDD) design control. Therefore, what sort of questions would one ask?

- We already know that one of the customer demands is size by leg diameter – what diameters?
- Why do they want it in different diameters – is there a special reason?

- What happens if they put it on a wrong brace because of the diameters given?
- How will they determine different diameters?
 - colour
 - inches or milimetre

But, before you can do this you need to know the questions. Therefore, it is good to start a PDS *pro forma*. In the reference text, one has been given, you do not need to stick to this. Some companies have their own version of a PDS; some people develop their own over the years; and some have nothing. But, in all cases, the PDS is fluid as something new will always crop up that needs to be asked.

Case Study: OTC Knee Support

For the purposes of the description of the elements of the PDS, I shall be using the OTC Knee Support as a vehicle. I am going to stick to this group of devices for clarity only.

In the case of this case study, one would think it is a simple problem, and little needs to be done. *Wrong!* Some may say this is a simple design modification and a PDS is not required. *Wrong!* At all stages of a product's life, whether brand new or being modified, stick to the PDS process; it will be worth it in the long run.

For the purposes of the examination of the PDS in detail, I am going to try to extract items that would be generic to all of the case study items; therefore, I am going to offer as the 'generic PDS'; I am then going to look at the individual case studies in more detail to illustrate where the differences lie.

3.2.3 Customer Section

I am going to lay this out just as one would in real life; therefore, the discussion is going to be minimal. However, to get over the fact that this would be both boring and uninteresting, I am going to give a little bit of an introduction to each section.

This is where all of your discussions with end users, patients, everyday folk, or marketing department pays you dividends. All of the regulatory bodies like to see user input (and as stated before it *really is* a design requirement); this section makes it explicit. However, all of the specification items within the PDS will have been found from one source or a multiple of sources; therefore, it is worth using the final column (called source) to make this explicit. This is not only for the regulatory bodies, but also for the person that follows on from you, but as an *aide-memoire* for yourself. (You will be surprised to know how many research students forget the identity of at least one important source and, then, have to spend weeks trying to refind it!)

Table 3.1 Example Customer Section of the PDS (Generic)

Item	Detail	Source
Leg orientation	It would be beneficial for the device to be universal, but if it is to be L&R, then marking should be obvious; the same applies for front and rear.	Focus group meetings
Colour	Men were not concerned about colours (except for pink). Ladies would like colour ranges to match outfits. Men: Beige, Blue, Cherry Red, Football team colours? Ladies: Pastels, Not yellow. Kids: Football team colours, cartoon characters, book characters; children's TV characters	Patient focus group
Size	Must be able to fit into a standard on-flight hand luggage case and leave room for other items.	End user focus group
Size	Should fit into standard packing item.	Packaging department

Table 3.1 gives some example specification items that could be attributed to any of the case study items related to the knee brace. **Note:** These are not design guides for use by *you*; they are examples only. You should *always* produce your own PDS and NOT copy someone else's!

3.2.4 Regulatory and Statutory Section

Once again, you need to conduct some research. We already know (from Chapter 2) that the device is Class I and 510(k) (exempt); that is self-certification. However, this does not mean *no certification*: it means the regulatory bodies are relying on *you* to stick to *their* requirements.

In the EU, this means the final design must meet the general and essential requirements as laid down in the MDD. In the USA, this means meeting the requirements of CFR21. How do you do this? You demonstrate it. How do you demonstrate it: with a document? Where does this document originate: in this section? Therefore, a good starting point is to use the Essential Requirements as found in the MDD (Table 3.2)². Therefore, the first entry in this section of the PDS will always be directly related to the essential requirements of the relevant authority.

This first entry into this PDS section will force the author to look at the relevant regulatory documentation and therefore base the rest of the

²This document is freely available on the Web, but you may wish to produce a tabular form as illustrated in Annexure.

Table 3.2 Memory Jogger to the Design Team That They are Designing a Medical Device		
Item	Detail	Source
MDD	Must meet essential and general requirements of MDD (e.g., use Annexure A for guidance).	MDD
CFR21	Must meet requirements as laid down in CFR21.	FDA

PDS on the questions posed. It will further force the author to start to look at any relevant standards and guidelines, mainly because it is impossible to claim you meet the requirements of either CFR21 or MDD without doing so! It is, therefore, quite common to see this section as a long list of standards, directive, and guidelines. However, this is essential as many devices, nowadays, cross-discipline boundaries and therefore, cross-standards, directives and guidance. It is down to the PDS author to make sure everyone that follows understands this!

Homework

Table 5.9 in Medical Device Design³ gives an excellent example of this section that needs no further explanation, nor expansion. However, as usual, there is some work for you to do. Using Annexure A, go through all of the essential requirements for a case study taken from Chapter 1. Do not take it lightly, but take due care and consideration. It matters not if you are in the USA or in the EU; it is a good exercise. When complete, see how this affects the development of your PDS as a whole. I assure you it will work wonders as it brings the PDS into clear focus.

3.2.5 Technical Section and Performance Section

Hopefully, you are starting to get the swing of this; it is pretty easy really. Think of what is required, write it down and give some references. It is not rocket science, but it is hard work.

These two sections are always confused with each other. The best way to think about the technical section, use the concept ‘what *we can use* and what *we cannot use*’ – it will also contain descriptions about the environment in which the device will operate; for the performance section, use the concept ‘what it *must not* do and what it *must* do’.

Therefore, some examples of an entry for the technical section would look like [Table 3.3](#).

³Ogrodnik, P. (2012) Medical Device Design, Ogrodnik, Academic Press, Oxford.

Table 3.3 Example Generic Technical Section Entries for the PDS for the Knee Support

Item	Detail	Source
Humidity	Anything from 0% to near 100% humidity	Customer focus group
Nominal operating temperature	Anywhere between -10°C and $+40^{\circ}\text{C}$	Customer focus group
Air quality	From clean to airborne grit (sand etc.)	Customer focus group

Table 3.4 Example Technical Section Entries for the PDS for the Knee Support Covering Contact with Tissues

Item	Detail	Source
Duration with the skin	The device is worn continuously for periods of up to 12 hours per day.	End user focus group
Sterility	Not near an open wound, but needs to be clean and disinfected before use.	End user focus group
Pressure necrosis	High, localised, long-term pressures can cause pressure necrosis, sores. Design to avoid this.	End user focus group

As you can see, the contents of [Table 3.3](#) sets out the operating parameters of the device. Now, this case study has a particular issue; as all of them have parts that are in contact with the skin, we need to ensure cleanliness, biocompatibility and so forth. For example how long will the device be in contact with the skin? Will it touch or be close to a wound? Is there any chance of irritation? Statements such as those in [Table 3.4](#) would cover these.

[Table 3.4](#) actually asks more questions of the lead designer as it tells them to make sure their design avoids known issues. This forces them to read around the subject and understand the discipline.

The performance section is the easier of the two; this is because all we need to consider is how the device should perform. Examples of entries for the knee brace are given in [Table 3.5](#).

Table 3.5 Example Generic Performance Section Entries for the PDS for the Knee Support

Item	Detail	Source
Pressure	When worn, the device should create a pressure of between 10 and 20 cm H ₂ O.	Literature ⁴

⁴When using literature as a source, it is a good practice to use Harvard referencing as it cuts down on text and makes it look good too. You can find Harvard referencing guides on any University Website.

Table 3.6 A Comparison of Performance Specification for the Elasticated Bandage in Comparison to the Knee Brace		
Item	Detail	Source
Elasticated knee support		
Pressure	When worn, the device should create a pressure of between 10 and 20 cm H ₂ O.	Literature ⁴
Knee brace		
Pressure	When worn, the device should create a pressure of between 10 and 20 cm H ₂ O.	Literature ⁴
Position	When worn, the device must not be able to change position relative to the knee.	Technical review ⁵
Position	The device must be able to articulate about the knee such that maximum extension = 0° and maximum flexion is = 100°. The point of rotation of the device = centre of rotation of the knee.	Technical review
Vertical load	When walking, the device must transfer 1.2*body weight across the knee. Based on 95% male, this value is 1.2 kN.	Literature
Torsional load	The maximum torsional load the device should transfer is 1 Nm.	Technical review

Now, let us look at the individual case studies in more detail, as it is this section that is likely to provide the difference between them.

Take for example the loading on the elasticated hose in comparison to the loading on the metal knee brace. The elasticated hose will only supply pressure; it has no ability to provide any structural support at all. It is certainly unable to provide and form resistance to torsion of the knee. Therefore, [Table 3.6](#) gives an illustration of the differences.

As you can see, if we were designing a knee support from scratch, the latter is far more demanding. We shall see how this affects our design when we come to solution selection.

⁵You are allowed to refer to your own documents if you do some calculations, some investigations experimental or otherwise, or some simulations. The same rule applies to citing and referencing.

3.2.6 Sales Section

This part is, in essence, the easiest one for the designer. But, it is the hardest for the sales and marketing team. The questions here are things like:

- price at point of sale?
- gross margin required?
- sales per month?
- sales per annum?
- states/countries in which they are to be sold?
- preferable colours?
- market trends?

Although you may not wish it, these simple items can have a massive impact on your selected design. Most of the questions are impossible to answer in a closeted office; they can only be answered by immersion in the market place. Therefore, this section is all about market research. If the marketing team is *you*, then you have a lot of work to do; if you have a marketing team to hand, then they have a lot of work to do! [Table 3.7](#) illustrates some typical entries into this section for the elasticated bandage.

3.2.7 Manufacturing Section

People often get this confused with sales. Do not ask me why, but they do! In this section, we need to look at manufacturing limitations that could affect our design. For example it would be great to use racing car based Kevlar in our designs; unfortunately, the manufacturing team

Table 3.7 Example of Sales Section Entries in the PDS for an Elastically Bandaged

Item	Detail	Source
Sales price	Average sales price is \$1–2.	Market research ⁶
Gross margin	25–30%.	Company target
Sales per annum	Maximum sales is 450,000 units per annum per size.	Market research
Sales trend	Market is heading towards supplying the elasticated bandage in packaging that looks like sterile packing but which really only keeps it clean.	Market research

⁶As with previous comments, you are allowed to have a market research report as your point of reference. Use HARVARD referencing!

Table 3.8 Example of Entry for the Manufacturing Section for the Elasticated Knee Brace

Item	Detail	Source
Animal products	Manufacturing facilities must not use animal by-products in their facilities.	Policy
Allergens	Manufacturing facilities must be free from nut products.	Policy
Sizes	Existing facilities can produce tubular elasticated bandage in diameters from 1" to 4" in ¼" steps, but in minimum lengths of 500 ft. Any other diameters would need new jigs and fixtures to be manufactured (max 7").	Manufacturing team
Lead time	The lead time from order of elasticated tubular to manufacture is 4 weeks.	Manufacturing team
Sizes	Elasticated strip can be bought 500 ft lengths at a range of sizes from 2" to 20" wide (in 1" steps).	Manufacturing team

have no experience or skills in using Kevlar. Therefore, is this a sensible choice for materials? What are the lead times for components? Do we have preferred manufacturers with certain skill sets?

All of these questions can be answered by including the manufacturing team in the development of this section of the PDS. Do not forget the limitation of animal-based substances; if you want to avoid the issue, just avoid their use; as this is a Class I device, there is no excuse or reason for creating this headache.

Table 3.8 gives an example of how the manufacturing section may look for the elasticated knee support.

Sometimes, as in the case of Table 3.8, the manufacturing team can offer suggestions that the designer may not have contemplated. More often than not, the manufacturing team *love* to get to help at this stage as it brings its own rewards later. Do not hesitate to talk to your manufacturers, submanufacturers, and component suppliers – you will be amazed at the payback!

3.2.8 Packaging and Transportation Section

As we discussed earlier, this part is often left to the end, but can be a real pain in the backside if it is. Again, we are looking at addressing market norms:

- How many to a box?
- What type of box? Anything special about the box?

- How are they stored?
- How are they transported?
- What conditions will they meet in transport?

Now, some people think this is going overboard, but I promise you, it is not. Suppose your piece of kit is for use in temperatures of +20°F to +50°F. You have designed it; therefore, all stays where it should in these temperature ranges, but the items are delivered in the cargo hold of an aeroplane. Will it go below 20°F? Maybe. Suppose it is being delivered in the back of a lorry in the height of summer? Will it go above 50°F? Probably. Should your packaging accommodate this, and, if so, how? Does the packaging need to be stored in a dry atmosphere? Are you worried if the box is dropped? [Table 3.9](#) attempts to address this for the elasticated brace and compares this with the mechanical knee brace.

Table 3.9 Example Entries for the Packaging and Transportation Section for the Elasticated Knee Support and the Knee Brace

Item	Detail	Source
Elasticated knee support		
Individual items	Packaged to look 'sterile' and 'medical' in an individual pouch	Market research
Grouped items	Packaging to incorporate hole to hang on display rack	Market research
Grouped items	Packing in boxes of 10; box also used a display item instead of the above	Market research
Grouped items	Distributed in boxes of 10. Standard packing box size is 24" × 24" × 10".	Packing department
Storage	Storage in a dry environment cannot be guaranteed	Packing department
Labels	Individual items and outer box to have labels giving information on size, lot number and CE mark.	Regulatory department
Mechanical knee brace		
Individual items	Likely to be a relatively expensive item and will be delivered in single units.	Market research
Grouped items	Single units but may be shipped as a bulk order of different sizes. Standard transportation boxes to be used.	Packing department and sales team
Individual items	Individual boxes need to look 'expensive'.	Market research
Labels	Individual items and outer box to have labels giving information on size, lot number, and CE mark.	Regulatory department
Storage	Need to be stored in a clean, dry environment and should be marked as such. Packaging to accommodate a moderate amount of humidity.	Sales team
Vibration	Transportation may cause vibration issues (localised marking, rattling, etc.). Packing to minimise this.	Packaging department

In reality, this section reminds the designer that, at the end of the day, it has to go from the manufacturing facility to someone's house. How does it get there and how do we get the people to buy it? As with the manufacturing section, if you get the packaging and transportation teams talking as soon as possible, things will be easier in the long run. Honestly, I have seen too many items that if they were just a little bit smaller, they could have fitted into a standard box and would have saved the company thousands of dollars and lots of shelf space!

Also, this section specifies the literature required in the boxes. As these are Class I, things are relatively simple, but you will need a declaration of conformity (EC) and instructions for use (all). How much detail goes into them is down to you, but just what should you include? You decide! But make sure you put it into this section.

3.2.9 Environmental Section

This section is all about the end game. There are so many rules and regulations concerning carbon footprints; recycling; handling of contaminated sharps, for example that they are too numerous to go into. However, you should always consider this aspect most carefully. Are there any regulations you really need to be concerned about? Does your packing need to be 100% recyclable? If not, how much? When your product reaches end of life, can it be thrown in the bin or does it need to be treated as a contaminated item? Is it likely to contain any electronics that may need special attention? Is carbon footprint an issue? All of these factors have increased this section from being a brief statement of intention to being a massive section of its own.

Homework

We have examined the PDS for the knee support. As usual, it is time for you to do some work. Rather than doing a PDS for each specific case study, this time generate a generic PDS for a wire cutter and for an orthopaedic cast. Try not to think of the solutions before hand; just write down what you think is required. We will be coming back to these in future chapters; therefore, you will be able to compare and contrast them.

CHAPTER 4

Conceptual Phase

4.1 A REMINDER ABOUT SPACE

I am writing this overlooking the hills of Dorset just north of Bridport.

So what?

Well, it is simple. If you read and understood anything about this phase of the design process, then it is all about creativity, about thinking new things, about being ‘in tune’¹ with your future product. Therefore, finding the ideal creative space is important; well this small spot of the English countryside is one of my ‘spots’ along with a small village in West Sussex near to Petworth, a small hamlet in the Staffordshire part of the Peak District just north of Uttoxeter, of course my garden, and a few very special pubs.

Notice, not one is my office at either work or University. They are *not* creative spaces and even with my best intentions never will be; great offices but not great thinking spaces. I have tried, I changed one to a lovely creative space, only to find that my line manager thought I had too much space and I am now sharing – which goes against all I said in the reference text.

When I need to be creative, I head to one of my ‘spots’, and soon the ideas start to flood out; you need to find your spots. This is the hardest thing for bosses to understand; they like neat ordered paper-free desks – this is fine for an accountancy office; it is *not* a design studio. If you work for yourself, it is easier to facilitate this space; if you work for someone else, you need to be brave and bold, and either ask for the space, or ask to be able to work in your ‘spot’.

The main thing is to have fun!

¹‘In tune’ has many sources – one is that if a single player in an orchestra is out of tune, then it all sounds bad. I prefer to think of it as resonance, when you are in tune with a system’s resonance, it begins to hum and shake all on its own; or, you get more out when in tune than when you are not.

4.2 THE RELATIONSHIP WITH YOUR PRODUCT DESIGN SPECIFICATION (PDS)

As I have stated earlier, your PDS describes the outcome. If it were a meal, it would describe the taste, colour, temperature, ethnic origins and so forth. However, it has not stated the ingredients or how they are to be ‘put together’ – that is, the menu. Your job is to find the menu that satisfies the hungry customer. Be successful and they will love you; produce a bulk standard item that they could have prepared, and they will hate you, forget the tip! Therefore, the PDS phase was all about them – what did they want? This part is all about you – what can you think of that will make them go ‘wow!’? This is where I get on my soap-box. There are so many so-called designers who push their ideals onto others in some sort of crusade, be it in clothing, in furniture or interior design, or in fashion. The job of a good designer is not to force an ideal, but to bring forth an idea that was sitting there waiting to come out. Think of the phrase ‘on the tip of my tongue’. When we cannot quite remember a name or a phrase, we often say it is ‘on the tip of my tongue’. Well, no matter how hard you look, you will never see it, but it is in the psyche waiting to come forth. In the same way, a need and a PDS are like the solution to a problem being on the ‘tip of the tongue’, but not able to be expressed; it is our job to now bring it out and express it at a full volume. If you are successful, your customer will grow to become customers.

You should recall that the overall design process is illustrated by [Figure 4.1](#).

You should notice that we are still in the expansion phase of the design process. The PDS has set the parameters, we are, now, to identify possible solutions and select one (or two) to work on in the embodiment phase.

Case Study: Wire Cutters

I have chosen this case study for this part of the text because of its potential for some extraordinary extensions of thought. These will enable me to exemplify creative thought and creative selection methods.

In the reference text, there are several models and techniques given, which enable you to develop potential solutions: let us assume that we

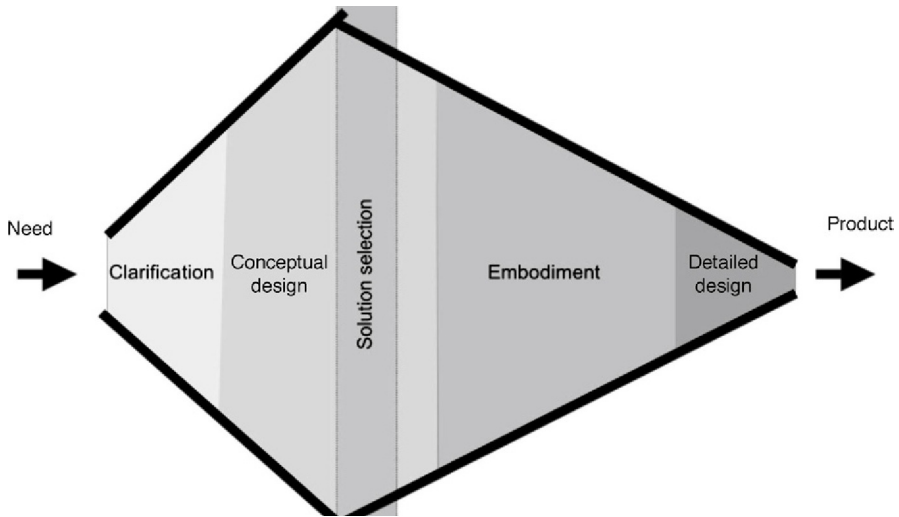


Fig. 4.1. Expansion-contraction design model.²

have successfully conducted a few based on a PDS for a wire cutter. Figure 4.2 and Table 4.1 give some ideas that have come from this phase; note, no assessment of their applicability has been undertaken. Also, note that I have used inversion techniques to use ‘shorten wire length’ as the aim, rather than ‘cutting wire’. This simple technique has enabled other ideas to be revealed.

In this instance, a table was sufficient to describe the solutions; sometimes, you will need to produce pictures/sketches to define your idea. This is easily done, and is wholly acceptable; therefore, the comments column (simply add ‘illustrated by Sketch 1’, etc.).

Homework

Using your own imagination, identify as many solutions as you can for a methodology for providing a temporary splint (refer to Case Study ‘Orthopaedic Cast’ Chapter 1). Tabulate them, sketch them, but your targets are: 10, idea is not bad; 15, good; 20, very good; 30, excellent.

The problem with this phase is that most people stop at *one* solution! Do not; you never know what is going to come out of the process. Just

²Taken from Ogrodnik (2012) *Medical Devices Design*, Oxford Academic Press.

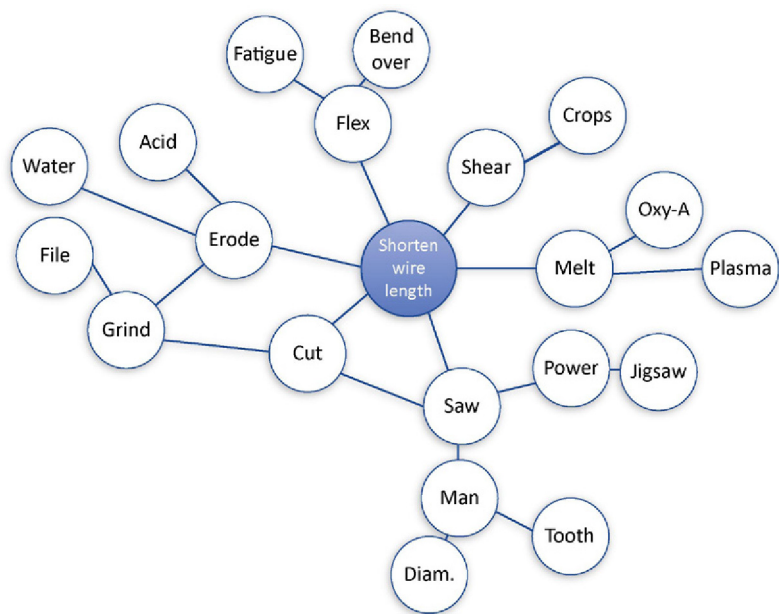


Fig. 4.2. Use of radial thinking to generate ideas for 'shorten wire length'.

Table 4.1 Potential Solutions That can Provide a Device That Will ‘Cut’ a Wire	
Solution	Comment
Scissors	Can cut thin sheets of metal, so why not?
Water jet	Used in manufacturing to cut metal profiles.
Laser	As above, but melts the metal.
Oxy-acetylene torch	As above.
Plasma jet	As above, but can vaporise the metal.
Bolt croppers	Often used for very large diameters
Manual saw	Commonly used item in metalwork.
Powered jigsaw	As above.
Electrical pliers	Used with copper cables.
Pincers	Can cut stone etc.
Cold-chisel and mallet	Often used in metalwork for cutting and trimming.
Diamond wire	Used in metalwork to cut hard top access rods etc.
File	Used to ‘wear down’ metallic objects, can be used to cut.
Standard wire cutters	Used for small diameter wires.
High-leverage wire cutters	Used for larger diameters than above.



Fig. 4.3. Neoprene knee support using 'hook and loop tape' strapping.

because you are working on a me-too project does not mean you do not apply design rigour; you may have just changed a me-too device into a me-only and make your company a lot of money!

Case Study: Hook and Loop Strapping for Knee Support

Within the context of the above statement, let us look at Case Study 'The OTC Joint Support' Chapter 1, but in particular the brace using hook and eye strapping ([Figure 4.3](#)).

Homework

Write down your suggestion for the need and the PDS for this requirement.

Now that I have left you with the hard bit, I am going to establish the table of solutions. Once again, I offer no assessment. The ideas may seem as daft, stupid, inadvisable, but that matters not; they are solutions!

Once again, it does not take long to build a list of solution methods. All are feasible, but we have not selected a solution yet.

This is where the PDS comes into force, all of these meet the need ‘to replace Velcro as a strapping method’; but do they meet the intricate details of the PDS? This is where, to use the vernacular, the ‘imposters to the throne’³ will be found.

4.3 SOLUTION SELECTION

Using Table 4.1 and selecting a few statements from a full PDS, let us start to select possible solutions. To start with, we need a filter. Consider the entrance examinations to university, what are they really for? They are a filter. If you have 500 people applying to a course with only 50 places, how do you manage to sift through all 500? You set an entrance exam that may cut it down to 100, simple logic really! We apply this logic to our long list of solutions. We know that all meet the basic need (i.e. all the students have a prerequisite list of school/college results), but we now look at them in detail.

Suppose our students must know about anatomy before starting the course; well, let us give them a really tough examination on anatomy – if they fail, they are out; if they pass they are through to the next phase.

4.3.1 Initial Screening (optional)

Within the PDS, there will be certain items that are *just so important* that they cannot be overlooked. This is why the reference text refers to weighting the PDS criteria. The higher the weighting, the more important the item.

³An old saying that means, basically, an imposter who pretends to be the ultimate but is far from it. Another saying would be the ‘Wolf in Sheep’s clothing’.

Case Study: Wire Cutters

Let us assume that our weighted PDS has come out with the following three main criteria with the highest weighting.

- Cut rounds/bars up to 6 mm diameter/profile.
- Must not produce excessive residues – shards, sharps, gases and so forth, from the process.
- Must not produce excessive heat as a part of the process.

We insert these into our table of solutions and analyse, no need for scores just 1 or 0 (Yes or No), because if it does not meet any of these criteria, then the solution is not suitable ([Table 4.3](#)).

Therefore, we have come upon four potential winners. If, however, you want to be more open at this point, you can. You can grade them from 0 to 5, if you wish. If we did this, what would the table look like?

Using the 0–5 criteria ([Table 4.4](#)) has resulted in many more potential solutions but has brought one new one into the frame for the top 5 (the diamond wire).

The arguments for using a binary (1/0) or 0–5 criteria are wide and varied. I suggest you use the one you feel most comfortable with and stick to it. *Do not*, however, change from one to another just because your favourite has been left out! Also, do not forget that this is not just your task alone; include your subcontractors and other people you have drawn together for your team. Remember, this is a collaborative design process!

Homework

Yep, it is that time again! Using both binary and 0–5 criterion, use the solutions given in [Table 4.2](#) and assess them against *three* PDS items that you consider to be the most important. Then, get some of your friends/colleagues to repeat the process and compare your answers to theirs – you may be surprised!

Homework

Using both binary and 0–5 criterion, use the solutions given in [Table 4.2](#) and assess them against three PDS, but this time against my *three* main criteria:

- Must be able to be applied and reapplied with ease.
- Must be adjustable to fit different diameter legs.
- Provide compression similar to or better than Velcro strapping.

A good example of the PDS-SELECTION combination working is that of the case study illustrated in Figure 1.14. In this case, it could be assumed

Table 4.2 Potential Solutions to Replace Velcro as a Strapping Method

Solution	Comment
Saw tooth strapping	As used on roller skates etc.
Shoe laces	Obvious.
Adhesive tape	As used in packing.
Glues/adhesives	Obvious.
Screws	Commonly used to hold things in place.
Cable ties	Commonly plastic, in extensive use.
String	Obvious.
Toggle clamps	Often used on luggage items.
Wire clamps	As used on storage jars and bottles.
Hooks and eyes	Used in brassieres.
Poppers	Used in clothing.
Buttons and button holes	As above.
Clothing belts	As above.

Table 4.3 Binary Criteria used for Selection of Main Contenders

Solution	Cut Rounds/ Bars up to 6 mm Diameter/Profile	Must Not Produce Excessive Residues – Shards, Sharps, Gases etc., from the Process	Must Not Produce Excessive Heat as a Part of the Process	Total
Scissors	0	1	1	2
Water jet	1	0	1	2
Laser	1	1	0	2
Oxy-acetylene torch	1	0	0	1
Plasma jet	1	0	0	1
Bolt croppers	1	1	1	3
Manual saw	1	0	1	2
Powered jigsaw	1	0	1	2
Electrical pliers	0	1	1	2
Pincers	1	1	1	3
Cold chisel and mallet	1	1	1	3
Diamond wire	1	0	1	2
File	1	0	1	2
Std wire cutters	0	1	1	2
High leverage wire cutters	1	1	1	3

Table 4.4 0–5 Criteria used for Selection of Main Contenders

Solution	Cut Rounds/ Bars up to 6 mm Diameter/Profile	Must Not Produce Excessive Residues – Shards, Sharps, Gases etc., from the Process	Must Not Produce Excessive Heat as a Part of the Process	Total
Bolt croppers	5	4	5	14
Diamond wire	5	4	5	14
High leverage wire cutters	5	4	5	14
Pincers	4	4	5	13
Cold chisel and mallet	4	4	5	13
File	5	3	5	13
Manual saw	5	4	4	13
Powered jigsaw	5	4	4	13
Water jet	5	2	5	12
Scissors	0	5	5	10
Electrical pliers	0	5	5	10
Std wire cutters	0	5	5	10
Laser	5	3	2	10
Oxy-acetylene torch	5	1	0	6
Plasma jet	5	1	0	6

that the designers were more concerned with identifying a new material for an established process rather than identifying a brand new process. Their aim to produce an ‘environmentally friendly’ cast using an environment friendly/sustainably resourced material. If that were truly the case, then the main criteria would be associated with the material itself. Which would you have first, the fact the material needs to be ‘green’ or that it ‘functions’. If it is green, but does not function as cast, well it is not much of use. If it functions but does not meet the environmental aims, then it has failed too. Therefore, I would propose that the main criteria used for filtering would include both the environmental aspects and the functional aspects. Meeting just one or the other alone would not achieve the desired outcome. However, meeting both comes up with something highly innovative.

4.3.2 Detailed Selection (Essential)

Once we have filtered our large list down to a few practical solutions (or if you wish, you can go straight to this phase missing out the initial filtering

4.5.1), we need to undertake a detailed analysis to pick the best solution. As I have said, you can go straight to this phase, but if you have 100 potential solutions that would be silly; if you only have 10, then it may be practical. Hopefully, you will have weighted criteria from your PDS, and hopefully, the actual number of individual criterion is large. It is worth noting that some will not be applicable at this stage (labelling, for example); in that situation, state 'n/a' but give a reason – never, ever, write n/a on its own!

There is a little reason to labour the selection process any further. If we did, we would soon run out of text and you would lose the will to read any further; we have much more to do.

4.4 SUMMARY

Well done, we have got through the hard part! Not the hardest in terms of technical content, but hardest because of the discipline required to do it properly. If I were to make an analogy, it is a bit like doing some exercise or sport. Everyone knows warming up is important, but nobody really likes doing it or really feels comfortable doing it; that is until they pull a muscle or damage a tendon! Unfortunately, by then, it is too late. I had warming up drummed into me (as I played cricket in my youth and was a bowler, warming up was important for both physical well-being and accuracy). Hopefully, I have done the same to you and drummed the importance of a good PDS and a good selection process into *you*.

CHAPTER 5

Embodiment Phase

5.1 A REMINDER ABOUT THIS PHASE

We are, now, at the stage where we start to put ‘flesh onto the bones’ of our skeleton of a project. In the previous chapters, we have expanded the initial concept into a series of potential solutions; we have whittled these solutions down to a small number of real candidates, and out of those, *one* candidate is the clear choice and with a couple in reserve if something goes wrong along the way. This concept of keeping a reserve is quite commonplace. To take football, soccer, rugby or any team sport as an analogy, it would be suicide to not have a potential substitute to call upon if a player gets injured; therefore, it would be if you took one solution only. If you did not have a backup plan sitting, waiting to be called upon, you would be, well to put it bluntly stupid. Notwithstanding this, there will be a clear outright option that stares you in the face, just as there would be a clear outright striker in the soccer team; this is your front runner, this is the one you put all of your main efforts into; this is the one you are banking on bringing you success. If you have done your PDS and selection processes properly, then this is the likely scenario.

So, just what is this phase about? It is bringing your solution from being a potential to a reality. Taking it from being a concept, through detailed design and to final sellable product. Therefore, it is a very large phase. It is also the phase where your collaborative design team really starts to work.

It is this phase that people neglect for this classification in particular. Because this class is self-certifying, it does not follow that the embodiment phase is any less rigorous. It probably means that the embodiment is relatively easy, but no less rigorous.

Just as I described in the reference text, and as illustrated in [Figure 5.1](#), if you are able to get everyone to work together along the same path, simultaneously, while communicating with one another, then you will find things move quickly and with relative ease (unlike this sentence!).

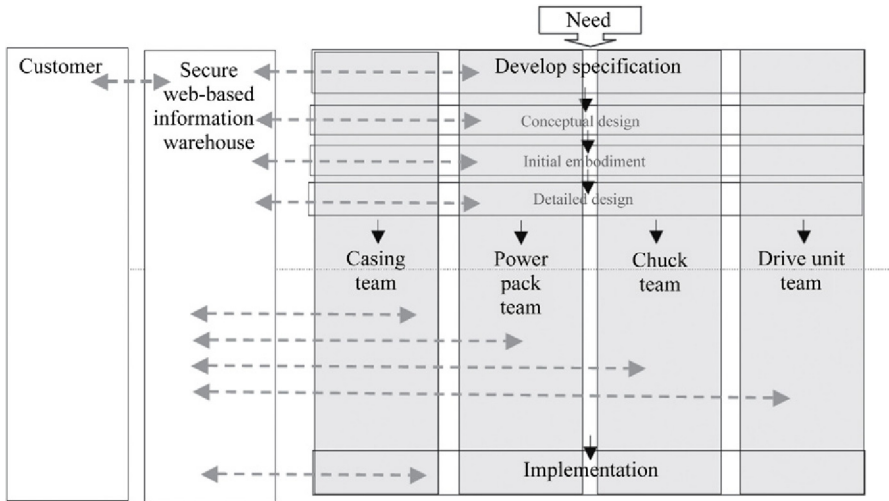


Fig. 5.1. Holistic model.¹

Whatever process you decide to use for your design model, you will still need to produce:

- an initial embodiment
- some form of prototype for initial evaluation
- final designs for the whole, individual parts, packaging, labels and the instructions for use.

Try to do all of this on your own, then, well, you are on your own!

5.2 INITIAL EMBODIMENT – OR FIRST PROTOTYPE PHASE

Even though this is first prototype, there is no less rigour applied then to the final design. In fact, the more effort spent here, the fewer changes will be needed to make your *first prototype* into the *final design*. To use writing a book as an analogy, if, in the first instance, you spend more time considering what you are putting down, onto paper,² the less your editor needs to do to turn your behemoth of a tome into a *page turner*.³

¹Taken from Ogrodnik (2012), *Medical Devices Design*, Academic Press, Oxford.

²Oops, sorry showing my age – this should read typing into my computer screen.

³A page turner is a colloquial term for a book that you just have to read cover to cover; no matter what you do, you just cannot put it down – you must keep reading.

It is also the phase where the real mistakes are made. Think of it as the foundations for a building, get them wrong and all else fails. Therefore, try and get things right from the start. An old colleague of mine had a great phrase:

*Don't just do the right things, do things right – first time.*⁴

I have added *first time*, the first part of the phrase is his. This is the time when you need to *do things right*.

Furthermore, this is the phase where you are likely to rely on all of the initial research you conducted to produce your PDS. It is also likely to be the phase where you start to identify some unknowns that were not even thought of during the PDS phase. If there were a phase where research and development (R&D) fits, it is here, you will find that the two are indistinguishable.

Case Study: The Inflatable Cast

Figure 1.12 illustrated the inflatable cast. What would we consider to be the initial embodiment of this device? Does it need to be a physical embodiment? Nowadays, the multifarious aspects of computer-aided engineering means that we can get full 3D representations presented on a full 3D television screen; all that is missing is touch. However, touch and feel in the virtual world is not too far away, but in the meantime, we use rapid prototyping methods, and this does not mean 3D printing that is additive manufacturing. I mean the production of a realistic prototype in timescales of hours/days rather than weeks/months. Rapidity is relative – if your final product takes 5 years to make, 5 weeks to get a prototype is pretty quick!

Furthermore, computer-aided engineering is all encompassing, and we are able to do a variety of, as it is known, multi-physics analyses to determine the performance of a device. Therefore, the first prototype/embodiment could be virtual, but as sure as eggs are eggs, you will soon be asked for a real one for everyone to hold, touch and cuddle; therefore, be prepared. I have heard companies stating they do not produce any physical prototypes, but as yet, I have to find one for which this claim is anywhere near 100% true. We are just not virtual people – yet. Maybe when the new generation of children get to our positions, their experiences with the virtual world may make their transition to this state of mind a reality.

Homework

Think of the inflatable cast/support illustrated in Figure 1.12. What would you expect to see for the first embodiment/prototype? Produce a shopping list.

No peeking! If you did the homework correctly, your list should be pretty long – if it is only one item, you are completely off track. Equally, if it is 100 items, you are, also, completely off track.

⁴I attribute this to Dave Whitworth, a mad-keen Morgan fanatic.

This footnote contains the minimum I would expect.⁵

How many did you get? Are there any you think I missed? How many of you forgot the first three items? If your prototype is physical, be prepared for item 12 to be very expensive. A prototype can, easily, be 10× the cost of the real thing and is often many times more.

In essence, this should be the first draft of your design history file, and the basic starting block for your technical file (for the European CE mark). Is it all starting to make sense? Using a well-trodden methodology makes life so much easier; much easier than hacking your way through the design process like some demented sugarcane plantation owner who has drunk too much rum.

We have already seen the documentation for items 1, 2 and 3 in the list. Let us, now, go through all of the rest, in turn.

5.2.1 Detailed Drawings and Specifications of Components

It is without doubt that these items are the real description of your product. Each assembly, each individual component, each subroutine, and each little piece needs to be specified. The way to think about this is that you should be able to pass this description to somebody else; they should be able to source it and give you the item, whatever it may be, in a form that was exactly what you asked for. In some cases, this may be an engineering drawing; in some cases, this may be in the form of a written specification of a part; but in all cases, it is a complete description. If there is anything particular that requires attention by the supplier, then this should be on the sheet (sheet is used freely as it

⁵My suggestions:

1. Statement of need.
2. Product design specification.
3. Solutions and selection.
4. Detailed drawings of all components and assemblies.
5. Calculations/simulations demonstrating performance.
6. A résumé/summary of application of quality in design.
7. Results of any physical tests.
8. List of suppliers of components/materials (with approximate – but not too approximate – costs).
9. Sample labelling.
10. Sample IFU (single language, no point going multi-lingual yet).
11. Sample packaging.
12. A physical/virtual representation of the device as appropriate.

could be a pdf file or a virtual document). I will discuss manufacturing instructions later on.

The indisputable truth is that you will need some form of documentation that describes the product as a whole, as subcomponents, and as individual parts. Furthermore, these descriptions must be lucid and clear, and auditable. Therefore, my suggestion is to use written specifications and engineering drawings as and where applicable. Do not fall into the trap of using a supplier's simple catalogue number for a component – these can change. If you have to use a supplier's part number for a component, make sure it is one that is fixed to that component/item and that you check for revisions before you make an order. To do this, you need to have a specification for the component that includes a description and the supplier's name and part number.

Case Study: Orthopaedic Cast

If we examine all the solutions together, we get a better idea of how it all fits together in this embodiment phase. Each example from Figure 1.9 to Figure 1.14 provides a solution to a need for a 'support for an injured limb'. But, let us look at the detailed drawing aspects of each. What would we expect to see?

Figures 1.10, 1.13 and 1.14 are quite awkward. The final outcome of the device is wholly unpredictable. They are, essentially, an outcome of an assembly of components *in situ*. That is, the end user dictates the final shape and visual appearance. However, it is *you* who dictate the components. Therefore, the detailed drawings or detailed specifications would be for the component materials themselves. In the case of Figure 1.10, the suppliers making the foam supports will need to know the sizes, the grade of foam and the material itself. Does this need to be a drawing? I doubt it. A simple specification sheet would suffice such as that given in [Figure 5.2](#).

Note that both items have a supplier that has their own catalogue part number that can be referred to. However, it is the product description in the middle column that gives the real information that describes the item itself.

Note that, just with a drawing, the specification has part numbers, version numbers and authorisation. It is worth noting, at this point, that some auditors are pedantic about manufacturing instructions.

Growing Bones Ltd		
Component Specification sheet		
Produced by:	Authorised by:	Version: Date:
Part Number	Description	Supplier(s)
1.324562	100 mm × 50 mm × 50 mm Low density foam block No off: 2 per unit Material: polyurethane medical grade	Foam Co Ltd (item no 134.567) Blockfoam inc.
1.324563	150 mm × 25 mm × 50 mm Low density foam block No off: 2 per unit Material: polyurethane medical grade	Foam Co Ltd (item no 134.542) Blockfoam inc.
GBL-Spec1	Version 1.1 Page 1/1	Approved: t.h.e.boss 14-12-14

Fig. 5.2. Example specification sheet.

Being an engineer, as far as I am concerned, I do not specify the method of manufacture of the foam itself, nor do I need to tell the supplier how to cut the foam; if it comes to me within specification, then all is as it should be. However, some auditors would ask you for a full manufacturing process including those of your subcontractors. Unfortunately, there is little I can offer here apart from alerting you to keep this in the back of your mind. If you take this argument too far, it would mean having the instructions of how the oil company removed the oil from the ground right the way to when your foam arrives; clearly silly. To avoid this – if at all possible – use suppliers with quality certification.

5.2.2 Calculations/Simulations Demonstrating Performance and Quality in Design

I have merged these two sections together just for the purpose of clarity of thought. The reason being that it is likely that some aspects of the calculations will be driven from a quality viewpoint, and some of the quality decisions will have been driven from a need for a calculation. However, in the files, this may be far too demanding to review; therefore, it may be wise to split them. Do not forget, your files *may be* reviewed at some stage (even though this level is self-certificated, there is nothing stopping someone at some stage demanding a view of your technical files/design history files); therefore, your task is to make it as easy as

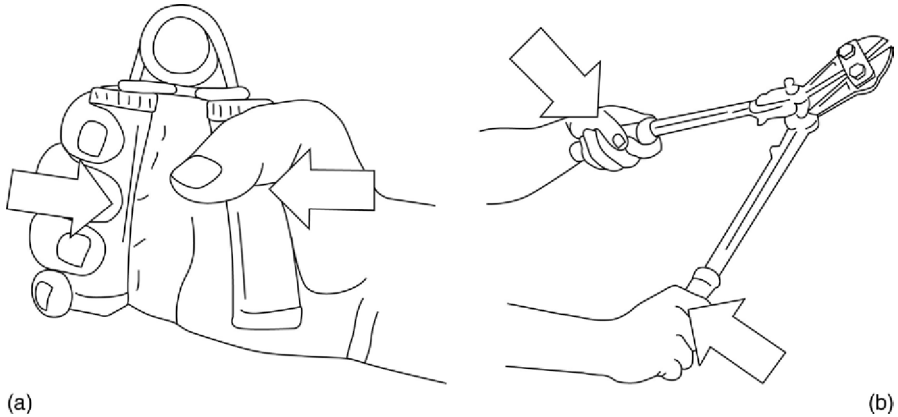


Fig. 5.3. Manual grip forces.

possible for them. Do not forget, they will know less about your subject than you do; therefore, you need to make life easy and write everything in that way.

Case Study: Surgical Wire Cutters

Suppose we have been tasked with determining the grip an average person can produce when using pliers/cutters. We identify two modes, a one handed grip in the palm of the hand, the other mode is having a handle in each hand and squeezing (as illustrated in Figure 5.3).

A quick bit of research results in an excellent source from NASA,⁶ although now superseded NASA-STD-3000 and NASA-STD-3001 are excellent sources of man-machine interface data, and as it is NASA, it should be pretty reliable.

Tables 5.1 and 5.2 illustrate several interesting facts. However, do we design the cut for the lowest strength or the highest strength? Clearly, we design the cutting action using the lowest force (254 N), but we design the cutter to withstand the maximum force (730 N) – why? Because the weakest person needs to be able to cut the wire, but the strongest must not be able to break the cutter itself. Figure 5.4 gives another valuable insight, and that is at the

⁶NASA (1995) Man-Systems Integration Standards Revision B, July 1995.

Table 5.1 NASA Grip Strength Data – Males ⁶				
Population		Percentiles, <i>N</i> (lb)		
US Air Force personnel, air crewmen	5th	50th or mean	95th	Population S.D.
Right hand	467 (105)	596 (134)	729 (164)	80.1 (18.0)
Left hand	427 (96)	552 (124)	685 (154)	71.2 (16.0)

Table 5.2 NASA Grip Strength Data – Females ⁶				
Population		Percentiles, <i>N</i> (lb)		
	5th	50th or mean	95th	Population S.D.
US Navy personnel – Mean of both hands	258 (58)	325 (73)	387 (87)	39.1 (8.8)
US Industrial workers – Preferred hand	254 (57)	329 (74)	405 (91)	45.8 (10.3)

point of cutting the separation of the handles should be about 60 mm. How would we report this? [Figure 5.5](#) gives a sample of a simple report.

Although [Figure 5.5](#) gives a brief research report, it could easily be added by inclusion of the graphs and tables presented earlier; even better would be an analysis of more than one source. However, as we are dealing with Class I devices, this is, probably, over the top.

Homework

I have found the values of gripping force for single-handed action. Your task is to produce a similar report using the action illustrated in [Figure 5.3b](#). Also, you should find more than one source (perhaps a minimum of three) for your data.

How do material selection and calculations fit into this schema? In exactly the same way as the report above, simply substitute the main body

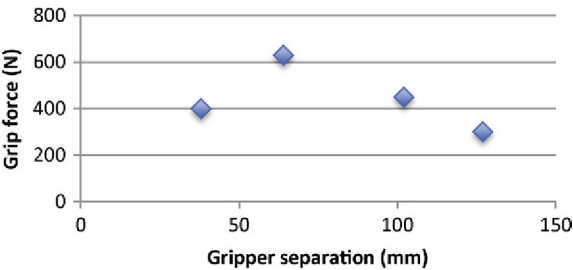


Fig. 5.4. Variation of grip strength with gripper separation.⁶

Growing Bones Ltd		
Report		
Conducted by:	Date:	Approved:
Aim: The aim of this research was to determine the grip force of a normal male/female in order to facilitate the design of wire-cutters (project no:14.0456-1) References: NASA, 1995, <i>Man-Systems Integration Standards Revision B</i>. Maximum: 730N Minimum: 254N Optimum gripper separation: 60 mm		
GBL-Reprt-1	Version 1.1 Page 1/1	Approved by: t.h.e.boss 14.1.14

Fig. 5.5. A very brief research report that would suffice as evidence.

of the report to describe what you have done and summarise the finding. Section 8.4 in the reference text gives another style of *pro forma* – there are no hard written rules about how the form you use looks. How the form looks is down to you; however, it is a controlled document that must have a version number, and so forth, and must be signed off and dated. Develop the form you like and stick to it.

To carry on with this point, let us look at how we would use it for material selection. The reference text illustrates several methods for material selection.

Case Study: Orthopaedic Casts

All of these items have one thing in common: they have items that are in contact with skin for some period of time. In most cases, they are longer than 1 day, and in some cases, it could be 30 days. Therefore, we need to be sure of biocompatibility. How would I go about this?

First: Market research. What materials do other people use? How do I do this? I go and get some proprietary items and do some eagle-eyed PI work. Also, I find some manufacturers of this type of material and ask their advice – do you remember that the subcontractors should be there in the first place? If so, this advice would be forthcoming. Good grief, I may even go to some exhibitions and actually ask other manufacturers – you will be amazed at how forthcoming people are. If you have brought any clinicians into the fold, they will give advice too.

Second: Materials research. I would look at the Web scientific papers databases (e.g. Google Scholar).⁷ I would enter as many keywords as I could think of and see what I would come up with. There are so many papers that compare these things that it is highly likely you will get a starting point. You never know you may even find a paper that gives you the answer directly. I would then use materials database engines (e.g. MatWeb).⁸

And

Third: If all else fails I am just going to have to go to the expense of doing it all from scratch (and that means all of the biocompatibility trials). Avoid this at all costs in Class I devices; you will *never* get your money back.

⁷scholar.google.com

⁸www.matweb.com

5.2.2.1 FMEA

Of all the things, you should not miss is FMEA. Once again, the reference text is the source. It is the FMEA that will probably drive most of your calculations, as you will be trying to avoid a failure! You need to be creative and think of any potential failure mode; some of which will be in your control, some will not – but you need to think of them. Do not be flippant with this section; a lack of FMEA in Class I items is commonplace but, as far as I am concerned, inexcusable.

Case Study: Knee Brace

If we are to perform an FMEA of the knee brace illustrated in Figure 1.3, we first need to think of the failure modes. Let us begin:

1. Strapping splits
2. Strapping undoes or loosens
3. Supports buckle
4. Supports snap
5. Support/strap connection breaks
6. Joint seizes
7. Joint breaks
8. Strapping not tight enough
9. Strapping too tight
10. Joint not aligned with knee joint
11. Opposite joint axes not aligned with each other

I do not intend to go through all of them one by one. However, let us look at one in detail; let us examine ‘Joint not aligned with knee joint’ (Table 5.3). How could this occur? What will be the issues? That is what FMEA is all about; it helps us to decide what failures we need to ‘design out’. As I said earlier, not doing this is an inexcusable error when designing any medical device of any classification.

I hope that this case study has demonstrated the power of FMEA. If we do our design blind, then we will always have problems. However, this case study has demonstrated that the IFU⁹ has led to design elements related to calculations, testing and contents of any instructions for use. Therefore, it is almost that I have presented things in the wrong order;

⁹Notice that the FMEA is starting to design the IFU too.

Table 5.3 Example FMEA for Knee Brace Failure Mode #10

Number	Failure	Effect	Cause	Rating				Remedial				
				Severity	Occurrence	Detection	RPN	Action	Severity	Occurrence	Detection	RPN
10	<i>Joint not aligned with knee joint.</i>	Leg is not able to be flexed.	IFU does not state this as a requirement.	2	5	3	30	Include a statement in IFU of this as essential to operation of device.	2	2	3	12
		Leg is not able to be flexed.	No way of detecting the joint is aligned with the knee.	2	5	5	50	Ensure centre of joint is visible such that this is obvious to user.	2	2	2	8
		Leg is forced to flex about wrong centre causing knee injury.	IFU does not state this as a requirement.	3	5	3	45	Include a statement in IFU of this as essential to operation of device.	2	2	3	12
		Leg is forced to flex about wrong centre causing knee injury.	No way of detecting the joint is aligned with the knee.	3	5	5	75*	Ensure centre of joint is visible such that this is obvious to user.	3	2	2	12
		Leg is suddenly forced to flex about wrong centre causing knee injury.	Strapping does not locate adequately.	4	2	5	80*	Testing required to demonstrate strapping does not fail under normal usage. IFU contains instructions to check strapping regularly.	4	2	2	16

(Continued)

Table 5.3 Example FMEA for Knee Brace Failure Mode #10 (Cont.)												
				Rating				Remedial				
Number	Failure	Effect	Cause	Severity	Occurrence	Detection	RPN	Action	Severity	Occurrence	Detection	RPN
		Leg is suddenly forced to flex about wrong centre causing knee injury.	System is overloaded by use; used outside of design criteria.	4	2	5	80*	IFU contains warnings about misuse of the device and states what 'normal' use means.	4	1	5	20
		Leg is forced to flex about wrong centre causing knee injury.	Manufacturing of the joint is poor causing eccentricity related to the markings.	5	2	5	50	Concentricity of the joint is to be stipulated in manufacturing instructions.	5	2	2	20

All initial RPN are above 25, and therefore, need remedial action. Some are above 50 (marked with an asterisk) and will need the remedial action sanctioned by a senior designer.

well, maybe I have but we are in chicken and egg land.¹⁰ Sometimes you will need to do an FMEA first to decide what to do; sometimes you need to do some preliminary work to even think about the FMEA. Which-ever you do first, the FMEA will appear, and it MUST do! You have been warned!

Homework

Yep you should know this by now! Your task is to undertake FMEA analyses for the remaining items in the list generated earlier. Use the guidelines in the reference text and try to think about the use, design, manufacture – anything that could cause the failure.

5.2.2.2 Optimisation

Although this is unlikely to be met in all cases, optimisation is a useful design tool. The reference text gives several optimisation methods and it is debatable how many would be useful for a Class I device. However, as far as I am concerned, there is no debate. If you have any design choice to make that can have an effect on performance, then you should, always, be finding an optimum value.

Case Study: Wire Cutters

Let us look at the wire cutters again, but this time in relation to optimisation. Those of you (and it should be all) that have read the reference text should recall that optimisation is all about achieving an objective function within a set of parameters. The wire cutters presented in Figure 1.4 are limited. We have already met the standard grip force according to NASA, and this is a fixed value. Therefore, the only way to increase cutting force is by increasing the length of the handles. Eventually, these handles would grow to resemble the handles in the large shearing cutters presented in Figure 1.7. Therefore, Figures 1.5 and 1.6 illustrate attempts to optimise the solution. Both use linkage mechanisms to act as force amplification, but in a much smaller space. In these cases, the objective function was to maximise force, and the boundaries to the problem was physical size.

5.2.2.3 Design for X

Do not, ever, ever forget D4X concepts in the initial prototype stage. I agree that some things cannot be decided upon at this stage, but even so they should be considered. I will expand on the reason(s) why. When one gets an idea in one's head about a design, it tends to stick. If it is just an idea, then it is possible to get the idea to change. However, once a

¹⁰Oh I hated my schoolmaster when he said 'Ogrodnik, you are mixing up the order of the egg and the chicken'. Since I did not know which came first, the chicken or the egg, how was I supposed to know I was mixing them up? Teachers! We love 'em and we hate 'em, both at the same time.

prototype has been made and tested, the chances of making significant changes becomes very hard indeed. Therefore, it is far better to think about D4X from the beginning, and build as much into your prototype as you can. If you do this, you will not only save you a lot of time later, in the final embodiment, but you will also not have to do so much retesting.

With this in mind, let us look at some D4X that may be important.

Case Study: Wire Cutters – Design for Sterilisation

As this is a reusable device, it will need to be sterilised. There are three common methods open to you: steam, ethylene oxide and irradiation. For most practical purposes, reusable devices need to be steam sterilisable. However, being sterilisable is not enough, they need to be washable too. Therefore, while you may have not used the final materials in the initial prototype, your overall shape may well be close to final. What do we need to consider at this stage?

- Blind holes? Are there any blind holes where dirt and detritus could stick. If there is a blind hole, can it be made not to be.
- Are any long, small-diameter holes really necessary?
- Will it fit? Does the device fit into a standard washing/sterilisation tray? If not, can it be dismantled so that it does?
- Will the proposed materials survive the cleaning and sterilisation process?
- Will cleaning and sterilisation cause any sticking or binding of threads and so forth?

As with previous items, if you have a group of staff from a CSD unit on your team, this advice will be forthcoming.

One thing you should not forget is the effect of cleaning and sterilisation on items that run on each other, that run on threads or which are push-fit or glued together. In the prototype stage, these things do not show themselves as issues; however, in real life, they can be real problems. Once again, FMEA will come to your rescue if you do it comprehensively!

Case Study: Knee Brace – Design for Assembly

Figure 1.3 illustrates a typical knee brace. One thing most designers forget, and especially at the prototype stage, is that someone has to be able to assemble the device. The problem with prototypes is that it is normally the design team that do the assembly and as such do not have the limitation of not knowing anything about the device. The knee brace is a good example of that issue. Firstly, how much of the device needs to be assembled at point of use; and secondly, how on earth are you going to describe the assembly process to them?

- Presumably, the device will come in a box with everything attached? If so, how are you going to allow for different diameter legs and relative position with the axis of the knee? If it is one-size-fits-all, this could be an issue.
- How is the device to be put onto the limb so that all is aligned perfectly (see FMEA case study earlier)? This is still assembly as the device is *not* a device until it is attached to the limb.
- How do the end users know that the straps have been secured correctly? How do they know how to adjust them?

There are two schools of thought here. You can either (a) rely on the instructions for use to solve this issue (not a good idea) or (b) design the issue out of the device (a good idea). If you were to go down path

(a) then avoiding written instructions (to avoid translation costs) but using pictures and diagrams instead (i.e. as an IKEA instruction leaflet). You will probably need some instructions for path (b) but their number will be, undoubtedly, fewer. However, the end user assembles the device in both instances. Once again having end users in your 'extended' design team to test your IFU will provide benefits.

The corollary of assembly is of course disassembly. It is just as important to consider how the end user is going to disassemble the device correctly just as it is to put it together. This is particularly important when it is a device that is being assembled and disassembled on a regular basis. But assembly, commissioning and decommissioning are essential parts of a device's life cycle and needs to be addressed. Once again, thinking about this in the prototype stage makes life a lot easier when developing the final embodiment.

Case Study: Orthopaedic Cast – Design for Environment

The elasticated supports illustrated in Figures 1.1 and 1.2 are not strictly casts but we shall start with them as they are examples of the same thing where one is more environmentally friendly than the other. Why I hear you ask? They are both elasticated materials. They are both used for roughly the same thing. But, what makes one more friendly than the other? The neoprene support, in Figure 1.2, has been designed for use and reuse (by the same person). The elasticated bandage in Figure 1.1 is likely to be used only once, or maybe a couple of times, before it is discarded. Therefore, a life cycle analysis suggests that for a long-term condition, the neoprene support would be more environmentally friendly than the bandage. However, for short-duration treatment, the materials used in the elasticated bandage are smaller in mass and volume, and therefore, less material is used. If you were selling these by the million, the potential environmental effects are significant, and consideration of this may give you a competitive edge over your competitors.

Case Study: Novel Materials for an Orthopaedic Cast

This simple analysis enables us to look at long-term casts illustrated in Figures 1.13 and 1.14. The structures of these casts have not really changed since they were first used in the eighteenth century. Effectively, they are a composite structure where the rigidity of the cast limits the movement of the limb, and therefore, restricts the motion of the broken bones. The usefulness of the device relies on the strength of the solid matrix. In between the matrix and the limb, fibres and cushioning are used to separate the solid matrix from the skin and offer some form of protection. This protective barrier has enabled new materials to be used for the solid matrix. Plaster of Paris is a simple material, but is messy and takes time to set. Modern solid matrices are constructed from polymer webbing infused with fast setting resins. However, they are not reusable. They are one-offs that are removed on a regular basis and at the end of treatment are disposed of. What can be done with them? Not much apart from landfill or incineration. However, the resources used to manufacture the matrix are drawn from the Earth and will not be reused. The example illustrated in Figure 1.14 is different. Here, the matrix is made from a wood derivative, which is from a sustainable source. Therefore, this solution ticks all the boxes when it comes to sustainable sourcing of materials. However, since it is a brand new matrix, the company would have had to conduct significant tests to demonstrate that the new matrix does not create any issues in relation to the patient themselves. Notwithstanding this, it is an excellent example of lateral thinking to come up with a more environmentally friendly solution.

Why was this case study important for the prototype? Simply put, if you are going against trends of use of materials – completely, you are going to have to prove what you are doing is absolutely safe and effective. Therefore, it is a debate whether until this is proven that the prototype has changed to become a real-life product. This is an example of a two-stage system; the first prototype would probably be a mock-up; the second would not be a prototype as such but is unlikely to be allowed to go to full open market until a controlled study has been conducted.

5.2.2.4 Validation and Verification

It is highly unlikely that your first prototype would ever be used on a real patient but number II may just. But, this does not mean that you should not be performing some initial validation and verification trials.

- Does the device do what it said it should?
- Can it be sterilised?
- Does the IFU enable end users to assemble and disassemble the device?
- Do the IFU and any further instructions enable the device to be used successfully by the end users?

All of the above, and more, can be answered during the prototype phase.

In reality, what you want from this phase is the ability to go straight to filing so that you can go straight to any end-user evaluation¹¹ (from a sales perspective, not a clinical perspective) that you may require. This is a hope and an aspiration; it may not be a reality, but we need to get as close as possible.

Once again, the PDS and your FMEA will have supplied all of the validation and verification tests that you need to conduct. Do not, also, forget tests that you need to do to ensure your device meets the essential requirements (as discussed earlier). In some instances, some initial

¹¹Unfortunately, the EU have made things confusing here. All medical devices marketing teams will use the term ‘clinical evaluation’ as developing opinions, facts and figures and comments from key opinion leaders to provide evidence in sales literature. The EU have decided to use the term ‘clinical evaluation’ as a report to be placed in the technical file and conducted before certification; therefore, before key opinion leaders (KOLs), get to use the device. Therefore, I have now called the former ‘end-user evaluation’ to avoid confusion.

evaluations could be done with the initial prototype; some will have to wait for the final product. Unlike higher classes, in this classification, you should not need to go straight to clinical evaluations (as described above) before you apply for certification. If, for some reason, you find that you do (mainly because your device is so new that there are no precedents), then you will need to have obtained your registrations, which means you need to have performed all the necessary tests on your initial prototype. Therefore, you may need a second prototype, termed the *functional prototype*. This functional prototype is so close to the real thing, that it is, to all intents and purposes, the real thing.

Note: This is a Class I device. There should be no need for you to enter in the expense of a clinical trial for this type of device, as it is low risk. This does not mean you are free from doing any form of validation, verification and clinical evaluation (using all of the FDA and EU terms).

5.2.2.5 Design for Manufacture

Last but, not least, arguably the most important aspect, after all if it cannot be made (to make some profit), then it is pointless going beyond prototype stage. However, you may well make some manufacturing shortcuts in the prototype stage that you would not do for the final product. For example, you may not use the best coating possible for the prototype – you may just get it painted. Why – to reduce the cost of the prototype down to the bare minimum. However, it is little point having a working prototype that is either unable to be manufactured at all, or that cannot be manufactured economically. Therefore, in the early prototype stage, one would consider design for manufacture to ensure the final design meet our requirements, and then forget the ones that are not essential to the functionality of the prototype.

5.3 PROTOTYPE TO FINAL DESIGN

5.3.1 Link Between this Stage and the Previous Stage

As I have tried to express to you, in the previous section, the investigations carried out on the preliminary prototype(s) should accelerate this phase. Do not even think of missing this phase out. It is going to be an essential element of your design history file/technical file and your clinical evaluation report.

Essentially, the same stages will be repeated, but in this stage, we are heading for the final item; therefore, there will be an emphasis on ‘tying up loose ends’.¹² All we are aiming for is the final prize, the device fully certified and on sale, and making us very, very rich!

Your sole target is to produce the final product; but in terms of regulatory requirements, your target is to produce the design history file/technical file and complete any validation and verification required. Therefore, it is no surprise that this is going to be laid out as if it were the DHF content of a technical file. As we have already conducted the investigation of the need and of the PDS, there is no need to repeat this, and they would go directly into the DHF. The same argument applies to the outcomes of the concept generation and selection processes. Therefore, in this section, we will be considering the final design aspects to ensure quality of the final product.

5.3.2 Detailed Drawings and Specifications

I would hope that, by now, you would have realised that these are auditable documents. Therefore, these all require an audit trail, which means version numbers, dates, authorisation and a register of changes. It is probably the latter that is more relevant to the DHF.

I do not think that I need to describe the meaning and importance of these documents; we have laboured this enough in both this and the reference text.

5.3.2.1 A Reminder About Logging Modifications

All quality procedures instruct the manufacturer to keep a register of changes/modifications to any aspect of the company’s activity. In the context of this book, this means any changes to a design of a component, a specification for a component, or any documentation related to that component. Now, there is *no* requirement within the CE marking process of the FDA process for this level of quality control; it *is* a requirement of either ISO9000 or ISO13485. However, both regulatory regimes require *Design Control*. I would argue that there is *no* control without monitoring and regulating of change. Therefore, I would further argue

¹²Tying up loose ends comes from the weaving industry where it literally means making sure the warp ends are closed off to ensure the fabric does not unravel.

that if you do not conduct this level of quality control, you are in breach of the fundamental tenets of both regulatory regimes, and therefore, do not meet their essential requirements; fail to undertake this important part of design control at your peril!

Therefore, if you make a change to a component, follow the basic tenets, as described in the reference text:

- Provide the statement of need for the change.
- Provide the specification for the change.
- Conduct the change.
- Record the change and undertake version number update.
- Put new document at the right place in the file.
- Put the old document in the repository.
- Put the record of change at the right place in the file.

Case Study: Wire Cutters – Design Modification

Consider the wire cutters illustrated in Figures 1.4, 1.5 or 1.6. Each of these has small bearing pins acting as joints. Assuming one of the pins is a simple M4 cap head screw, and that due to company preference, the material is to change from 440 stainless steel to 316 stainless steel; let us examine the documentation I would expect to see.

Firstly, there would be a new drawing for the pin and an old drawing for the pin. The new drawing would have a new revision number, and associated with that number would be a note on the drawing linking the revision number and the change made. The old drawing would have a line drawn across it, a note of the date, and a note of the change made.

Secondly, there would be a small report as in [Figure 5.6](#).

Growing Bones Ltd		
Record of Modification		
Conducted by: F.Smoit	Date: 14.1.14	Approved: T.H.E. Lead
Part Number: 04.250.23 Description: M4 Set Screw, 15 mm shank, 5 mm thread. Need: To avoid having mixed stainless steels it has been decided to move to a single grade throughout, in this case 316. Document changed: Drawing 04.250.23: Previous Version 1.2: New Version 1.3 Validation conducted: Report attached.		
GBL-RoM-1	Version 1.1 Page 1/1	Approved by: t.h.e.boss 14.1.12

Fig. 5.6. Example design modification report.

5.3.2.2 Transition from FMEA to Risk Analysis (RA)

I have laboured the FMEA aspect of quality in design. But, as we get toward the end of the project, things will have moved on from using FMEA to help in the design process to RA.¹³ I hope that by reading the reference text, you *know* that this is an essential part of the final phase of the process of taking your idea to a commercial product. I do not intend to go into how to conduct the RA; this is described fully in the reference text and in the ISO standard. However, I do intend to remind you of the difference(s).

The first thing to remember is that the RA form is similar to that of the FMEA form apart from its intention; $RPN = \text{Likelihood} \times \text{Severity}$ (and these are defined); if there is any remedial action, then one has to discuss residual risk or additional risk induced by the remedial action. Now, this all sounds a bit laborious; unfortunately, it is. Also, if you do not do this, you will get into serious trouble with the regulatory authorities as they are expecting you to have conducted a full RA. If you have read the reference text and have looked at ISO14971, you will know that the best pathway is to use the Annexure C pre-questionnaire;¹⁴ to use your own imagination to think of any other risks using Table E2 in ISO14972 or the edited version given as Table 9.2 in the reference text; and then to use the recommended RA form to analyse each risk identified. All of this will be a document of significant size and must reside in your technical file/design history file.

As with earlier comments, if you have performed the tasks contained within the previous sections with care and diligence, this should be an exercise that is time consuming, but one that is not overly demanding. However, you *must* be diligent. I can almost guarantee that if you do have an audit of any form (say you are introducing a higher class variant), then this document will be examined in very close detail.

5.3.2.3 Essential Requirements (Especially for EU)

If you are going onto CE marking, then you will need to address the Essential Requirements section of the Medical Devices Directive (MDD). Although it is, in all intents and purposes, the final act, it is important to consider it at this stage. To help you do this, Annexure A contains

¹³Remember to use the latest version of ISO14971 (or if it has happened by the time you get to read this its replacement)

¹⁴Given in Annexure C: Ogrodnik (2012), *Medical Devices Design*, Academic Press.

a *pro forma* for you to complete. However, at this stage, it is not for completion, but for advice. Indeed, the advice is very useful; it is a highly beneficial tool for those going down the 510(k) route; simply because it makes you check you have confirmed all of the requirements of a medical device. Meet all of these and you are well on the way to certification.

At this stage, however, it is to help you to decide on any tests, any evaluations, and any literature you need to evaluate. Best to do it at this stage than to leave it to the end, and only to find out that you have forgotten something important, and that ‘important something’ takes you right back to the start and delays the launch of the product.

Case Study: Implication of Essential Requirement 5 on This Stage

Let us remind ourselves of requirement 5:

The devices must be designed, manufactured and packed in such a way that their characteristics and performances during their intended use will not be adversely affected during transport and storage, taking account of the instructions and information provided by the manufacturer.

How would this affect the final embodiment stage? Well, clearly, it affects the choice of packaging. However, as I have stated so many times before, this should all have been covered in the PDS. Notwithstanding this, you will need to demonstrate that your packaging is able to protect your device during transportation – so you will need to do some tests. Does it matter if your device gets wet? If it does, then you will need to use the standard symbol for ‘keep me dry’ on the package. Does the device need careful transportation or can it be put into the postal system? If it is the former, then everyone needs to know. If it is the latter, are you sure of this and have you tested it?

Completing the form given in Annexure A is not just a formality, it is a final check that you have done what is required. I am afraid assuming it is okay is not enough – you need to be able to demonstrate that everything is okay.

Homework

Oh come on! You did not think I was going to let you get away without doing this one, did you?

Using any of the wire cutters illustrated in Figures 1.4, 1.5 and 1.6 as an example; complete the table given in Annexure A as best you can. Try not to be too pedantic, but do try and think about the implications of the questions asked in the table to the overall question ‘have I finished and is my product ready for launch?’

5.3.2.4 Validation, Verification and Clinical Evaluation

Things start to get a bit messy here due to the mixed terminology of the EC, the FDA and common practice. It is the EU that have messed things up as they have used the term Clinical Evaluation Report¹⁵ for an essential document for all devices. This does not mean getting a clinician to evaluate your device (which is what I expect the phrase to mean). However, if you conduct a validation and verification study correctly, the clinical evaluation document should fall out, almost, automatically. Equally, if you conducted your PDS part of the process correctly, all of the tasks required to complete these three aspects of certification should have been specified by *you*. Equally, the previous section (essential requirements) also gives you pointers as to what you should be doing to meet the requirements of this section.

You do have one happy thought though. Being a Class I device, there is no requirement to conduct a *clinical trial* before you can move forward to final certification. Just to remind you, a clinical trial is a blind or double blind study conducted *before* your device is given a CE mark or FDA clearance to market. Therefore, you would need to apply for permission from the regulatory bodies to just undertake the trial, then you would need to find a university hospital to conduct the trial, then you would receive a very large invoice. Therefore, being a Class I device is good news. But, this does not divulge you from the responsibility of showing that your device has some purpose, that it offers some benefit.

Case Study: Wire Cutters – Validation and Verification

Even though one might have thought one could go through this by precedent, well it is true one could. After all, if one has produced a direct copy of something else, then if all is the same, the performance should be the same; all one has to do is prove they are the same. There is the crux; *prove they are the same*. How will you prove they are the same? First comparing dimensions and materials: the same – tick. Then, maybe you could perform a cutting test by increasing the diameter of wire and stopping when one cannot cut. If yours stops at the same (or better) than the precedent, then they are the same. Job done.

If yours is not a copy, but a brand new design, what is the additional information you require. Clearly, your design should perform better than the precedents, so perhaps measurement of cutting force? Maybe a microscopic examination of the wire ends to show a lack of sharp edges. Maybe proof that it cuts larger diameter wires. The last is to show that it is washable and sterilisable.

¹⁵For further information on the clinical evaluation report, obtain the latest version of meddev 2.7.1 from ec.europa.eu.

5.3.2.5 IFUs, Labelling, Other Instructions and Markings

Although you may think this is not a part of your product, under all medical devices regulations around the world, I am afraid all three are! You do not have a completed product until you have attached all of your labels, until you have included your IFU, until you have included any other instructions required and until you have added all the permanent marking required on the device itself. You may think this is pedantic; it is not. Remember the final outcome of this last and final embodiment is the ability to go forward to creating sales; without marking, labelling and IFUs, we cannot – therefore, without these, the embodiment is *not* finished.

Case Study: Wire Cutters – Marking

It is a requirement for all medical devices to be identifiable. Not only should they look like what they should be (that is just obvious), but they should have a part number and a lot number. If the device comes apart into individual pieces, all parts should be marked with the same. If the device is to be sold in the EU, it further requires the CE mark. Note, as this is a Class I device, it only needs the CE symbol; it does not require a notified body number.

5.4 SUMMARY

I would hope that this chapter has demonstrated the effort that goes into producing the initial and the final embodiment. I hope that I have demonstrated that you need to take a holistic approach to this phase and, further, that it is the initial PDS phase that is, still, in control. Equally, I hope I have demonstrated that one has to perform design control methodologies, FMEA, RA and Validation, Verification and Clinical Evaluation reporting.

CHAPTER 6

The Home Run

6.1 A SUMMARY OF ACTIVITY

I would hope that you will have recognised that my efforts have been targeted at you meeting the design control requirements of both the Food and Drug Administration (FDA) and the Medical Devices Directive (MDD). If you have followed the holistic approach, whereby sub-contractors have been included in the design process, then you are well on the way to meet the Good Manufacturing Practice (GMP) requirements of the FDA (and of the CE mark too). We have a few things to put into place and we will be ready for certification.

6.2 THE TECHNICAL FILE

Even though this may seem to be overboard for the FDA, I think it is one of the good aspects of the MDD. The MDD forces you to produce a *bible* of your device. A document that is sacrosanct; and it is virtually impossible to change without some form of divine intervention; okay, that is going a bit over the top but you get my drift – it is the document of documents as far as your device is concerned. If you are to have a CE mark, then this document is essential: if you are only looking at FDA clearance to market, I would suggest it is darn good practice.

Why do I say this? There is no need for you to have ISO13485 or one of the ISO9000 families to be a Class I medical device manufacturer. In the USA, some Class II devices are 510(k) exempt too; therefore, there is no need here either. That means you do not have the quality assurance procedures in place that ensure that the quality of your product is controlled. The technical file forces you to implement a selection of procedures that is the bare minimum to meet both MDD and GMP requirements. Therefore, I would argue, it is just good design practice to produce a technical file and create it in such a way that it meets the requirements for a Design History File (DHF) and, if required, a 510(k)

submission too. It is also worth noting that the FDA *Design Control Guidance For Medical Device Manufacturers*¹ states that the DHF is cross-referenced to ISO 13485 and ISO 9000. Therefore, a good technical file will not only relate to a good DHF, but will also help with the preparation of a 510(k) if rules change and your device jumps up to being non-exempt.

It is up to you in which order you meet the technical file requirements as illustrated in Table 6.1; there is *no* proscriptive layout. You need to find what suits you and make it work. However, one caveat is to make sure you make all of these aspects highly visible to the auditor. Table 6.2 describes standard contents for an FDA 510(k) submission.

Table 6.1 Standard Contents Expected in a Class I Technical File

Section	Subsection	Content	Suggestions for the FDA 510(k) Equivalent
Product design, description, drawings and specification			Device description.
		Description of the device and its components. Description of variants of the product.	
		Intended use.	
		Accessories.	
		Diagrams/drawings.	
		Technical and physical description of hardware.	
		Software specification.	
Production methods			In design controls.
		Summary of manufacturing method/ production flowchart.	
Classification			In: Cover letter. In: Substantial equivalence discussion.
		Class.	
		Rule.	
		Rationale.	
Essential requirements			Effectively in design controls but affects all.
		Normally, it is required to submit an essential requirements checklist based on Annex I of 93/42/EEC as modified by 2007/47/EC.	

¹ FDA, 1997. Design Control Guidance For Medical Device Manufacturers, FDA. Available from www.fda.gov.

Table 6.1 Standard Contents Expected in a Class I Technical File (*cont.*)

Section	Subsection	Content	Suggestions for the FDA 510(k) Equivalent
		A summary of the evidence demonstrating compliance with each essential requirement needs to be provided as well as a link to the evidence itself. Where standards have been used to demonstrate compliance, they need to be listed.	
		Where an essential requirement is considered not to be applicable, an appropriate rationale for the determination needs to be provided.	
Standards applied		What standards are used.	In: Declarations of conformity and summary reports.
Risk management			In: Design controls.
		Application of risk management has been undertaken according to ISO 14971:2007. The following documents are presented:	
		Contents.	
		Conclusion.	
		Overall residual risk/risk/benefit.	
		Competence for the persons involved (risk management, medical/user and technical).	
Material and processing			
		Material in direct or indirect contact with the patient or user.	
		Concentration of substances, if applicable.	
	Biocompatibility		Biocompatibility.
		Biocompatibility tests performed/evaluations/rationales.	
	Sterilisation		Sterilisation and shelf life.
		Sterilisation method.	
		Validation of sterilisation process.	
		Residual testing/bioburden evaluation. Packaging validation.	
Labelling and instructions for use			All in proposed labelling.
	Labels		
		Description of different labels.	

(Continued)

Table 6.1 Standard Contents Expected in a Class I Technical File (*cont.*)

Section	Subsection	Content	Suggestions for the FDA 510(k) Equivalent
		Information included on the labels.	
		Placement of labels, if applicable.	
	Instructions for use		
		Description of different manuals, leaflets, and so forth.	
		Information included.	
	Translation procedure		
Life time/shelf life			In: Sterilisation and shelf life.
		Aging tests, if applicable.	
Verifications and validations			EMC and electrical safety. Performance bench – testing. Performance testing – animal. Performance testing – clinical. Software.
		Performed safety tests according to standards.	
		Verification and validation of hardware according to the client's requirements.	
		Verification and validation of software.	
		Other performed tests.	
Evaluation of clinical data			Substantial equivalence. Discussion. Performance testing – clinical.
		Should be performed according to MEDDEV 2.7.1. (The level of information required is dependent upon the level of risk posed by the device.)	
Declaration of Conformity			Indications for use statement. Declaration of conformity and summary reports.
		Contents.	
		Signature and date.	

Table 6.1 Standard Contents Expected in a Class I Technical File (*cont.*)

Section	Subsection	Content	Suggestions for the FDA 510(k) Equivalent
Other applicable directives			In: Declarations of conformity and summary reports.
PMS			In: Design control.
		Specific PMS process for this product, if applicable.	
		Specific post market clinical follow up for this product, if applicable.	

Table 6.2 Suggested Contents Listing for a Technical File to Meet the Requirements of a DHF

Section	Subsection	Contents
Title page		As described in the reference text.
Product approval		
	Part drawings and specifications	Do not forget to insert a flowchart of the production methodology. If you subcontract wholly, this would be procurement and QC. If you manufacture in house, you will need copies of work instructions.
	Approved manufacturers	A list of manufacturers, which components they supply and which is the preferred supplier. ²
	Declaration of conformity	Not only your declaration of conformity but also analysis of class (MDD and FDA) and also copies of any paper work from either FDA or notified body or competent authority.
	Essential requirements	Tick sheet as discussed before.
	Risk analysis	RA as discussed before.
	IFU	As discussed before.
	Labelling	As discussed before.
Clinical evaluation		
	Adverse incidents report	Update annually: check both MAUDE and MDD websites.
	Clinical evaluation report	Follow MEDDEV 7.2.1.

(Continued)

² **Note:** You must have an approved suppliers file that contains their current level of certification (ISO13485 etc.) and their actual certificates. If you do not use ISO registered suppliers, then you will need to perform your own audits: not something, I recommend.

Table 6.2 Suggested Contents Listing for a Technical File to Meet the Requirements of a DHF (cont.)

Section	Subsection	Contents
Validation and verification		
	Substantial equivalence statement	If it is pretty much the same as everyone else's, all you need to do for the rest is to show that it is the same. Saves a lot of time!
	Packaging, sterilisation and shelf life evaluation	As discussed before.
	Biocompatibility evaluation	As discussed before, but if there is none, say so; do not leave it blank.
	Software evaluation	As discussed, but if there is none, say so; do not leave it blank.
	Electrical and electromagnetic safety evaluation	As discussed, but if there is none, say so; do not leave it blank.
	Performance evaluation	If you have any evaluations from design calculations, from the prototype stage, or from final evaluation, this is where they go.
	Animal products evaluation	Do you use any? Is it made in an environment where they exist. Make sure this says there are not any or you will have a lot of work to do.
Technical file amendments		Simply records of all changes in chronological order with documentation that due process has been undertaken. You can attach the deceased documents here or put into the repository as separate items.
PMS		
	Procedure	Insert a copy of the procedure.
	Records	Insert records of PMS: tasks undertaken, actions and notifications (hopefully none of the latter).
Repository		
	Design history	Historical records of the design process from start to the technical file production (may need separate volume); i.e., all of the original design records, meeting records, etc.
	Deceased documents	Those that have changed since the TF was signed off as a valid product for release.

One section that you will notice is missing is the repository; the place where dead drawings go! This needs to be at the back after Section 'Document Modifications' in which your records of modification reside. The other bit that is missing, which I feel is essential, is all of the original design records that led to the technical file itself. Certainly, I would sug-

gest there needs to be a record of all of the stages being signed off, and records providing evidence of this. These are important aspects of the whole device and are an essential aspect of a DHF.

Here, a quandary lies: do you really want an auditor to see everything or just what they need to see? I would suggest one does not want to air ones dirty washing in public.³ I am not saying that you should hide issues from an auditor, far from it, but the more they have to look through, the greater the cost to you as they are paid by the day/hour. Therefore, once again, make your technical file easy to follow and not large, cumbersome and unwieldy.

I have come up with a compromise that seems to work. I, therefore, suggest this contents page for your technical file.

Nowadays, thanks to the advent of multi-page scanners that save documents as PDFs, this is easily stored electronically. There is no real need for a paper version; however, I still have a paper version in my office just in case required!

Why did I put the drawings and specifications at the front? Simply because this is going to be your most common point of referral as I hope you will be making lots of your new designs.

6.3 A NOTE ABOUT MANUFACTURING

I would imagine that most reading this will be likely to use subcontractors for their components. If so, try and use those with recognised quality certificates, as this makes your life a lot easier. If you do, all you need to do is to produce a table as in [Table 6.3](#), and put this table, along with their respective certificates in an *approved manufactures* file.

All you need to do is to have sections in the file for each company, and their respective certificates inserted. If the item is of particular importance, you may wish to include a copy of an initial report detailing how you arrived at the decision that they could be included in your file. However, as you have already spoken with these people in your design pathway (have you not), the choice was clear and obvious!

³ An old English saying that means ‘have arguments and have secrets but only let those who really need to know, know’.

Table 6.3 Approved Manufacturer's Pro Forma				
Company	Contact Details	Quality Audited by	Certificate Details	Parts
Insert company name	Insert the contact details, person's name, telephone number etc.	Hopefully audited by certificate (ISO9000 or ISO13485).	Certificate number and expiry date.	The parts, components, and items they are approved to supply.

Do not forget to keep this file up-to-date; it is the first thing auditors go to and it is the most common non-conformance!

6.4 A NOTE ABOUT POST MARKET SURVEILLANCE (PMS)

Just because you have a Class I, or a 510(k) exempt device, you are not excused from performing and undertaking PMS. Indeed, you have exactly the same responsibilities as any other medical device manufacturer. Therefore, you *must* have a PMS in place. The reference text and MEDDEV⁴ guidelines put all of this into perspective for you.

- You must be able to collect comments – good and bad.
- You must review these comments regularly and decide what to do.
- You must be able to react to adverse incidents in the time frames stipulated by both the FDA and the MDD.
- You must be able to conduct preventative actions.
- You must be able to notify the authorities in a timely manner.
- You must be able to recall devices in both a timely and a correct manner.

None of the above can be done without a procedure being in place, and you cannot get your certification without one being in place (because if you have not, you will be telling lies and a long holiday in a correctional institute is waiting for you).

6.5 THE FINAL FURLONG⁵

We made it! We have got to the point of application for certification/clearance to market. And, here the two systems differ (the reference text and their respective websites help).

⁴ http://ec.europa.eu/health/medical-devices/documents/guidelines/index_en.htm
⁵ Taken from horse racing, the final furlong is the last few yards before the finish line and is where the jockeys, horses, commentators and spectators go into frenzy.

6.5.1 EU

The registration is conducted with a single EU state's notified body (in the United Kingdom, the MHRA). This is conducted with a single form, downloadable from the relevant website, completed and sent in with the appropriate fee. A few weeks later, a letter arrives with your company's registration number, and you can now stick a CE mark all over it and sell it all over Europe. This is a once-only payment, unless you wish to make a change (such as change of address).

6.5.2 FDA

You register your company on the FDA website. Once you have paid your annual fee and you have received all of the relevant login details, you can begin listing your 510(k) exempt devices. However, you will need to renew registration every year.

6.6 CONTINUAL IMPROVEMENT

Once complete, the technical file is not a dead document. It is *alive*. The whole point of having a PMS system in place is to create an environment where continual quality improvement happens. A quality system is based on continual improvement. Things change. Things that could be sterilised last week stop working this week because a fluid in the washing/sterilisation process changes. Things that were able to be assembled last week cannot be assembled this week because they no longer hold that size of screwdriver. All of these silly little issues pop up, but it is part and parcel of your mandatory requirements as a medical device manufacturer to keep on top of them – therefore, do so!

REFERENCES

- European Union, 1993. Medical Devices Directive 93/42/EEC as amended by 2007/47/EC.
- European Union, 2009. Clinical Evaluation: Guide for Manufacturers and Notified Bodies, MEDDEV 2.7/1.
- European Union, 2010. Classification of Medical Devices, MEDDEV 2.4/1.
- European Union, 2013. Medical Devices Vigilance System, MEDDEV 2.12.1.
- FDA, 1997. Design Control Guidance for Medical Device Manufacturers.
- FDA, 2010. 21 CFR Subchapter H Part 860.
- ISO/British Standards Institute, 2012. Risk Management for Medical Devices, ISO14971:2012.
- ISO/British Standards Institute, 2003. Medical Devices – Quality Management Systems –Requirements for Regulatory Purposes, ISO13485:2003.
- Ogrodnik, P., 2012. *Medical Devices Design: Innovation from Concept to Market*. Elsevier Imprints/Academic Press, Oxford.
- NASA, 1995. Man–Systems Integration Standards Revision B, NASA-STD3000.

Relevant Websites

- MEDDEV documents. http://ec.europa.eu/health/medical-devices/documents/guidelines/index_en.htm.
- FDA guidance. <http://www.fda.gov/MedicalDevices/default.htm>.

Essential Requirements¹

Product No:

Product Name:

Version: 1.0

Approved by:

Date:

General statement:

This device is designed and manufactured to a quality system conforming to Medical Devices Directive 93/42/EEC Annexure II as amended by 2007/47/EC.

The [XXX Co] Quality Manual contains all relevant processes, procedures, and guidelines.

Where applicable, the relevant ISO, BS, and ASTM standards are used in the design process.

I GENERAL REQUIREMENTS

To ensure that essential requirements 1–6 are met, the following standards have been used:

[Insert section – insert all the standards and guidelines you have used.]

[In the next table, DO NOT leave any comment box empty, all must be addressed: therefore, you should have a tick or an n/a with comments addressing every point.]

¹EC (1993) *Medical Devices Directive 93/42/EEC as amended by 2007/47/EC*.

Requirement	Subsection	Claim ✓ - requirement met n/a - not applicable	References	Comment
1. The devices must be designed and manufactured in such a way that when used under the conditions and for the purposes intended, they will not compromise the clinical condition or the safety of patients, or the safety and health of users or, where applicable, other persons, provided that any risks that may be associated with their intended use constitute acceptable risks when weighed against the benefits to the patient and are compatible with a high level of protection of health and safety. This shall include: – reducing, as far as possible, the risk of use error due to the ergonomic features of the device and the environment in which the device is intended to be used (design for patient safety), and – consideration of the technical knowledge, experience, education, training and where applicable, the medical and physical conditions of intended users (design for lay, professional, disabled or other users).		All of these are essential requirements and have to be ticked.	In this column, insert the position/place in your technical file/DHF or quality manual where this is addressed.	In this column add additional comments such as how it is addressed, standards used, guidelines used or papers cited.
2. The solutions adopted by the manufacturer for the design and construction of the devices must conform to safety principles, taking account of the generally acknowledged state of the art. In selecting the most appropriate solutions, the manufacturer must apply the following principles in the following order: – eliminate or reduce risks as far as possible (inherently safe design and construction), – where appropriate, take adequate protection measures including alarms, if necessary, in relation to risks that cannot be eliminated, – inform users of the residual risks due to any shortcomings of the protection measures adopted.				
3. The devices must achieve the performances intended by the manufacturer and be designed, manufactured, and packaged in such a way that they are suitable for one or more of the functions referred in Article 1 (2) (a), as specified by the manufacturer.				

4. The characteristics and performances referred in Sections 1, 2, and 3 must not be adversely affected to such a degree that clinical conditions and safety of the patients and, where applicable, other persons are compromised during the lifetime of the device as indicated by the manufacturer, when the device is subjected to the stresses that can occur during normal conditions of use.				
5. The devices must be designed, manufactured and packed in such a way that their characteristics and performances during their intended use will not be adversely affected during transport and storage taking account of the instructions and information provided by the manufacturer.				
6. Any undesirable side effect must constitute an acceptable risk when weighed against the performances intended.				
	a. Demonstration of conformity with the essential requirements must include a clinical evaluation in accordance with Annexure X.			

II REQUIREMENTS REGARDING DESIGN AND CONSTRUCTION

Requirement	Subsection	Claim ✓ - requirement met n/a - not applicable	Reference	Comment
7. Chemical, physical, and biological properties				
7.1. The devices must be designed and manufactured in such a way as to guarantee the characteristics and performances referred to in Section I of the ‘General requirements.’ Particular attention must be paid to:	- the choice of materials used, particularly as regards to toxicity and, where appropriate, flammability, - the compatibility between the materials used and biological tissues, cells, and body fluids, taking account of the intended purpose of the device.	In this column, you add a tick if the point is applicable and has been met; add n/a if not applicable.	In this column, insert the position/place in your technical file/ DHF or quality manual where this is addressed.	In this column, add additional comments such as how it is addressed, standards used, guidelines used, or papers cited. If you have inserted n/a you must say why it is n/a here.
7.2. The devices must be designed, manufactured, and packed in such a way as to minimise the risk posed by contaminants and residues to the persons involved in the transport, storage, and use of the devices and to the patients, taking account of the intended purpose of the product. Particular attention must be paid to the tissues exposed and to the duration and frequency of exposure.				
7.3. The devices must be designed and manufactured in such a way that they can be used safely with the materials, substances, and gases with which they enter into contact during their normal use or during routine procedures; if the devices are intended to administer medicinal products, they must be designed and manufactured in such a way as to be compatible with the medicinal products concerned according to the provisions and restrictions governing these products and that their performance is maintained in accordance with the intended use.				

7.4. Where a device incorporates, as an integral part, a substance which, if used separately, may be considered to be a medicinal product as defined in Article 1 of Directive 2001/83/EC and which is liable to act upon the body with action ancillary to that of the device; the quality, safety and usefulness of the substance must be verified by analogy with the methods specified in Annexure I to Directive 2001/83/EC. For the substances referred to in the first paragraph, the notified body shall, having verified the usefulness of the substance as part of the medical device and taking account of the intended purpose of the device, seek a scientific opinion from one of the competent authorities designated by the Member States or the European Medicines Agency (EMA) acting particularly through its committee in accordance with Regulation (EC) No 726/2004 (*) on the quality and safety of the substance including the clinical benefit/risk profile of the incorporation of the substance into the device. When issuing its opinion, the competent authority or the EMA shall take into account the manufacturing process and the data related to the usefulness of incorporation of the substance into the device as determined by the notified body. Where a device incorporates, as an integral part, a human blood derivative, the notified body shall, having verified the usefulness of the substance as part of the medical device and taking into account the intended purpose of the device, seek a scientific opinion from the EMA, acting particularly through its committee, on the quality and safety of the substance including the clinical benefit/risk profile of the incorporation of the human blood derivative into the device. When issuing its opinion, the EMA shall take into account the manufacturing process and the data related to the usefulness of incorporation of the substance into the device as determined by the notified body.				
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(Continued)

Requirement	Subsection	Claim ✓ - requirement met n/a - not applicable	Reference	Comment
Where changes are made to an ancillary substance incorporated in a device, in particular, related to its manufacturing process, the notified body shall be informed of the changes and shall consult the relevant medicines competent authority (i.e., the one involved in the initial consultation), in order to confirm that the quality and safety of the ancillary substance are maintained. The competent authority shall take into account the data related to the usefulness of incorporation of the substance into the device as determined by the notified body, in order to ensure that the changes have no negative impact on the established benefit/risk profile of the addition of the substance in the medical device. When the relevant medicines competent authority (i.e., the one involved in the initial consultation) has obtained information on the ancillary substance, which could have an impact on the established benefit/risk profile of the addition of the substance in the medical device, it shall provide the notified body with advice, whether this information has an impact on the established benefit/risk profile of the addition of the substance in the medical device or not. The notified body shall take the updated scientific opinion into account in reconsidering its assessment of the conformity assessment procedure. (*) Regulation (EC) No. 726/2004 of the European Parliament and of the Council of 31 March 2004 laying down Community procedures for the authorisation and supervision of medicinal products for human and veterinary use and establishing a European Medicines Agency (OJ L 136, 30.4.2004, p. 1). Regulation as last amended by Regulation (EC) No. 1901/2006.				

7.5. The devices must be designed and manufactured in such a way as to reduce to a minimum risk posed by substances leaking from the device. Special attention shall be given to substances that are carcinogenic, mutagenic or toxic in reproduction, in accordance with Annexure I to Council Directive 67/548/EEC of 27 June 1967 on the approximation of laws, regulations and administrative provisions relating to the classification, packaging and labeling of dangerous substances (*). If parts of a device (or a device itself) intended to administer and/or remove medicines, body liquids or other substances to or from the body, or devices intended for transport and storage of such body fluids or substances, contain phthalates that are classified as carcinogenic, mutagenic or toxic to reproduction, of category 1 or 2, in accordance with Annexure I to Directive 67/548/EEC; these devices must be labelled on the device itself and/or on the packaging for each unit or, where appropriate, on the sales packaging as a device containing phthalates. If the intended use of such devices includes treatment of children or treatment of pregnant or nursing women, the manufacturer must provide a specific justification for the use of these substances with regard to compliance with the essential requirements, in particular of this paragraph, within the technical documentation and, within the instructions for use, information on residual risks for these patient groups and, if applicable, on appropriate precautionary measures. (*) OJ 196, 16.8.1967, p. 1. Directive as last amended by Directive 2006/121/EC of the European Parliament and of the Council (OJ L 396, 30.12.2006, p. 850).				
7.6. Devices must be designed and manufactured in such a way as to reduce, as much as possible, risks posed by the unintentional ingress of substances into the device taking into account the device and the nature of the environment in which it is intended to be used.				

(Continued)

Requirement	Subsection	Claim ✓ - requirement met n/a - not applicable	Reference	Comment
8. Infection and microbial contamination				
8.1. The devices and manufacturing processes must be designed in such a way as to eliminate or reduce as far as possible the risk of infection to the patient, user and third parties. The design must allow easy handling and, where necessary, minimise contamination of the device by the patient or vice versa during use.				
8.2. Tissues of animal origin must originate from animals that have been subjected to veterinary controls and surveillance adapted to the intended use of the tissues. Notified bodies shall retain information on the geographical origin of the animals. Processing, preservation, testing and handling of tissues, cells and substances of animal origin must be carried out to provide optimal security. In particular, safety with regard to viruses and other transmissible agents must be addressed by implementation of validated methods of elimination or viral inactivation in the course of the manufacturing process.				
8.3. Devices delivered in a sterile state must be designed, manufactured and packed in a nonreusable pack and/or according to appropriate procedures to ensure that they are sterile when placed on the market and remain sterile, under the storage and transport conditions laid down, until the protective packaging is damaged or opened.				
8.4. Devices delivered in a sterile state must have been manufactured and sterilised by an appropriate, validated method.				

8.5. Devices intended to be sterilised must be manufactured in appropriately controlled (e.g. environmental) conditions.				
8.6. Packaging systems for nonsterile devices must keep the product without deterioration at the level of cleanliness stipulated and, if the devices are to be sterilised prior to use, minimise the risk of microbial contamination; the packaging system must be suitable taking account of the method of sterilisation indicated by the manufacturer.				
8.7. The packaging and/or label of the device must distinguish between identical or similar products sold in both sterile and nonsterile condition.				
9. Construction and environmental properties				
9.1. If the device is intended for use in combination with other devices or equipment, the whole combination, including the connection system must be safe and must not impair the specified performances of the devices. Any restrictions on use must be indicated on the label or in the instructions for use.				
9.2. Devices must be designed and manufactured in such a way as to remove or minimise as far as is possible: – the risk of injury, in connection with their physical features, including the volume/pressure ratio, dimensional, and where appropriate, ergonomic features, – risks connected with reasonably foreseeable environmental conditions, such as magnetic fields, external electrical influences, electrostatic discharge, pressure, temperature or variations in pressure and acceleration, – the risks of reciprocal interference with other devices normally used in the investigations or for the treatment given, – risks arising where maintenance or calibration are not possible (as with implants), from aging of materials used or loss of accuracy of any measuring or control mechanism.				

(Continued)

Requirement	Subsection	Claim ✓ - requirement met n/a - not applicable	Reference	Comment
9.3. Devices must be designed and manufactured in such a way as to minimise the risks of fire or explosion during normal use and in single fault condition. Particular attention must be paid to devices whose intended use includes exposure to flammable substances or to substances that could cause combustion.				
10. Devices with a measuring function				
10.1. Devices with a measuring function must be designed and manufactured in such a way as to provide sufficient accuracy and stability within appropriate limits of accuracy and taking account of the intended purpose of the device. The limits of accuracy must be indicated by the manufacturer.				
10.2. The measurement, monitoring, and display scale must be designed in line with ergonomic principles, taking account of the intended purpose of the device.				
10.3. The measurements made by devices with a measuring function must be expressed in legal units conforming to the provisions of Council Directive 80/181/EEC (20).				
11. Protection against radiation				
11.1. General	11.1.1. Devices shall be designed and manufactured in such a way that exposure of patients, users and other persons to radiation shall be reduced as far as possible compatible with the intended purpose, while not restricting the application of appropriate specified levels for therapeutic and diagnostic purposes.			

11.2. Intended radiation	11.2.1. Where devices are designed to emit hazardous levels of radiation necessary for a specific medical purpose, the benefit of which is considered to outweigh the risks inherent in the emission, it must be possible for the user to control the emissions. Such devices shall be designed and manufactured to ensure reproducibility and tolerance of relevant variable parameters.			
	11.2.2. Where devices are intended to emit potentially hazardous, visible and/or invisible radiation, they must be fitted, where practicable, with visual displays and/or audible warnings of such emissions.			
11.3. Unintended radiation	11.3.1. Devices shall be designed and manufactured in such a way that exposure of patients, users, and other persons to the emission of unintended, stray, or scattered radiation is reduced as far as possible.			

(Continued)

Requirement	Subsection	Claim ✓ - requirement met n/a - not applicable	Reference	Comment
11.4. Instructions	11.4.1. The operating instructions for devices emitting radiation must give detailed information regarding the nature of the emitted radiation, means of protecting the patient and the user, and ways of avoiding misuse and eliminating the risks inherent in installation.			
11.5. Ionising radiation	11.5.1. Devices intended to emit ionising radiation must be designed and manufactured in such a way as to ensure that, where practicable, the quantity, geometry, and quality of radiation emitted can be varied and controlled taking into account the intended use.			
	11.5.2. Devices emitting ionising radiation intended for diagnostic radiology shall be designed and manufactured in such a way as to achieve appropriate image and/or output quality for the intended medical purpose while minimising radiation exposure of the patient and user. 20 OJ No L 39. 15. 2. 1980, p. 40. Directive as last amended by Directive 891617/EEC (OJ No L 357, 7.12.1989, p. 28).			

	11.5.3. Devices emitting ionising radiation, intended for therapeutic radiology shall be designed and manufactured in such a way as to enable reliable monitoring and control of the delivered dose, the beam type and energy and, where appropriate, the quality of radiation.			
12. Requirements for medical devices connected to or equipped with an energy source				
12.1. Devices incorporating electronic programmable systems must be designed to ensure the repeatability, reliability, and performance of these systems according to the intended use. In the event of a single fault condition (in the system), appropriate means should be adopted to eliminate or reduce, as far as possible, consequent risks.				
	a. For devices that incorporate software or that are medical software in themselves, the software must be validated according to the state of the art taking into account the principles of development life cycle, risk management, validation, and verification.			
12.2. Devices where the safety of the patients depends on an internal power supply must be equipped with a means of determining the state of the power supply.				
12.3. Devices where the safety of the patients depends on an external power supply must include an alarm system to signal any power failure.				

(Continued)

Requirement	Subsection	Claim ✓ - requirement met n/a - not applicable	Reference	Comment
12.4. Devices intended to monitor one or more clinical parameters of a patient must be equipped with appropriate alarm systems to alert the user of situations that could lead to death or severe deterioration of the patient's state of health.				
12.5. Devices must be designed and manufactured in such a way as to minimise the risks of creating electromagnetic fields that could impair the operation of other devices or equipment in the usual environment.				
12.6. Protection against electrical risks				
Devices must be designed and manufactured in such a way as to avoid, as far as possible, the risk of accidental electric shocks during normal use and in single fault condition, provided the devices are installed correctly.				
12.7. Protection against mechanical and thermal risks	12.7.1. Devices must be designed and manufactured in such a way as to protect the patient and user against mechanical risks connected with, for example resistance, stability, and moving parts.			
	12.7.2. Devices must be designed and manufactured in such a way as to reduce to the lowest possible level the risks arising from vibration generated by the devices, taking account of technical progress and of the means available for limiting vibrations, particularly at source, unless the vibrations are part of the specified performance.			

	12.7.3. Devices must be designed and manufactured in such a way as to reduce to the lowest possible level the risks arising from the noise emitted, taking account of technical progress and of the means available to reduce noise, particularly at source, unless the noise emitted is part of the specified performance.			
	12.7.4. Terminals and connectors to the electricity, gas or hydraulic, and pneumatic energy supplies, which the user has to handle, must be designed and constructed in such a way as to minimise all possible risks.			
	12.7.5. Accessible parts of the devices (excluding the parts or areas intended to supply heat or reach given temperatures) and their surroundings must not attain potentially dangerous temperatures under normal use.			
12.8. Protection against the risks posed to the patient by energy supplies or substances	12.8.1. Devices for supplying the patient with energy or substances must be designed and constructed in such a way that the flow rate can be set and maintained accurately enough to guarantee the safety of the patient and the user.			

(Continued)

Requirement	Subsection	Claim ✓ - requirement met n/a - not applicable	Reference	Comment
	12.8.2. Devices must be fitted with the means of preventing and/or indicating any inadequacies in the flow rate, which could pose a danger. Devices must incorporate suitable means to prevent, as far as possible, the accidental release of dangerous levels of energy from an energy and/or substance source.			
12.9. The function of controls and indicators must be clearly specified on the devices. Where a device bears instructions required for its operation or indicates operating or adjustment parameters by means of a visual system, such information must be understandable to the user and, as appropriate, the patient.				
13. Information supplied by the manufacturer				
13.1. Each device must be accompanied by the information needed to use it safely and properly, taking account of the training and knowledge of the potential users, and to identify the manufacturer.				
13.2. Where appropriate, this information should take the form of symbols. Any symbol or identification colour used must conform to the harmonised standards. In areas for which no standards exist, the symbols and colours must be described in the documentation supplied with the device.				

13.3. The label must bear the following particulars:	a. The name or trade name and address of the manufacturer. For devices imported into the Community, in view of their distribution in the Community, the label, or the outer packaging, or instructions for use, shall contain, in addition, the name and address of the authorised representative where the manufacturer does not have a registered place of business in the Community.			
	b. The details strictly necessary to identify the device and the contents of the packaging especially for the users.			
	c. Where appropriate, the word 'STERILE'.			
	d. Where appropriate, the batch code, preceded by the word 'LOT' or the serial number.			
	e. Where appropriate, an indication of the date by which the device should be used, in safety, expressed as the year and month.			
	f. Where appropriate, an indication that the device is for single use. A manufacturer's indication of single use must be consistent across the Community.			

(Continued)

Requirement	Subsection	Claim ✓ - requirement met n/a - not applicable	Reference	Comment
	g. If the device is custom made, the words 'custom-made device.'			
	h. If the device is intended for clinical investigations, the words 'exclusively for clinical investigations'.			
	i. Any special storage and/or handling conditions.			
	j. Any special operating instructions.			
	k. Any warnings and/or precautions to take.			
	l. Year of manufacture for active devices other than those covered by 'c'. This indication may be included in the batch or serial number.			
	m. Where applicable, method of sterilisation.			
13.4. If the intended purpose of the device is not obvious to the user, the manufacturer must clearly state it on the label and in the instructions for use.				
13.5. Wherever reasonable and practicable, the devices and detachable components must be identified, where appropriate in terms of batches, to allow all appropriate action to detect any potential risk posed by the devices and detachable components.				

13.6. Where appropriate, the instructions for use must contain the following particulars.	a. The details referred to in Section 13.3, with the exception of 'c' and 'd'.			
	b. The performances referred to in Section 3 and any undesirable side effects.			
	c. If the device must be installed with or connected to other medical devices or equipment to operate as required for its intended purpose, sufficient details of its characteristics to identify the correct devices or equipment to use to obtain a safe combination.			
	d. All the information needed to verify whether the device is properly installed and can operate correctly and safely, plus details of the nature and frequency of the maintenance and calibration needed to ensure that the devices operate properly and safely at all times.			
	e. Where appropriate, information to avoid certain risks in connection with implantation of the device.			

(Continued)

Requirement	Subsection	Claim ✓ - requirement met n/a - not applicable	Reference	Comment
	f. Information regarding the risks of reciprocal interference posed by the presence of the device during specific investigations or treatment.			
	g. The necessary instructions in the event of damage to the sterile packaging and, where appropriate, details of appropriate methods of resterilisation.			
	h. If the device is reusable, information on the appropriate processes to allow reuse, including cleaning, disinfection, packaging, and, where appropriate, the method of sterilisation of the device to be resterilised, and any restriction on the number of reuses. Where devices are supplied with the intention that they be sterilised before use, the instructions for cleaning and sterilisation must be such that, if correctly followed, the device will still comply with the requirements in Section I.			

	If the device bears an indication that the device is for single use, information on known characteristics and technical factors known to the manufacturer that could pose a risk if the device were to be reused. If in accordance with Section 13.1, no instructions for use are needed, the information must be made available to the user upon request.			
	i. Details of any further treatment or handling needed before the device can be used (for example sterilisation, final assembly, etc.).			
	j. In the case of devices emitting radiation for medical purposes, details of the nature, type, intensity, and distribution of this radiation. The instructions for use must also include details allowing the medical staff to brief the patient on any contraindications and any precautions to be taken. These details should be covered in particular.			
	k. Precautions to be taken in the event of changes in the performance of the device.			

(Continued)

Requirement	Subsection	Claim ✓ - requirement met n/a - not applicable	Reference	Comment
	l. Precautions to be taken with regard to exposure, in reasonably foreseeable environmental conditions, to magnetic fields, external electrical influences, electrostatic discharge, pressure or variations in pressure, acceleration, thermal ignition sources etc.			
	m. Adequate information regarding the medicinal product or products that the device in question is designed to administer, including any limitations in the choice of substances to be delivered.			
	n. Precautions to be taken against any special, unusual risks related to the disposal of the device.			
	o. Medicinal substances, or human blood derivatives incorporated into the device as an integral part in accordance with Section 7.4.			
	p. Degree of accuracy claimed for devices with a measuring function.			
	q. Date of issue or the latest revision of the instructions for use.			